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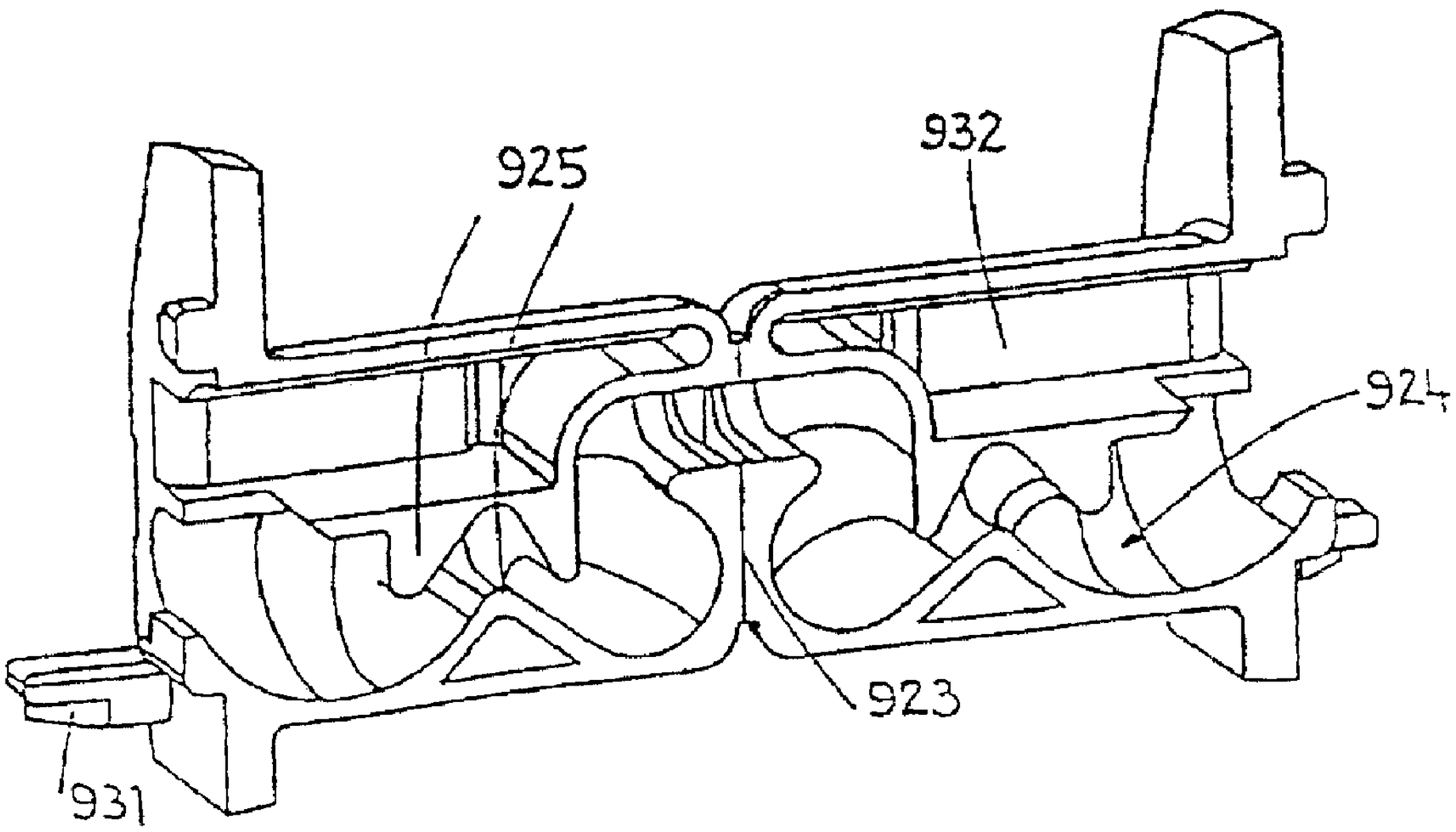
(54) Title: INHALER FOR MULTIPLE DOSED ADMINISTRATION OF A PHARMACOLOGICAL DRY POWDER



(57) Abrégé/Abstract:
A mouth piece for an inhaler has a mouth tube containing an atomizer path. The atomizer path has first and second channel sections. The first channel section has at least one baffle, while the second channel section has first and second channel portions located on a first lower and a second higher level, respectively. The first portion of the second channel section is located on the lower level and has an enlarged volume so as to deposit coarser particles contained in an air stream, which are ineffective for inhalation. The second portion of the second channel section is located on the higher level and is in communication with the outlet, so that only particles having a size effective for inhalation are transported by the air stream to the second, higher level and through the outlet of the mouth tube. The outlet has the shape of a horizontally arranged slit provided in the end face of the mouth tube.

20152-1242D

Abstract

A mouth piece for an inhaler has a mouth tube containing an atomizer path. The atomizer path has first and second channel sections. The first channel section has at least one baffle, while the second channel section has first and second channel portions located on a first lower and a second higher level, respectively. The first portion of the second channel section is located on the lower level and has an enlarged volume so as to deposit coarser particles contained in an air stream, which are ineffective for inhalation. The second portion of the second channel section is located on the higher level and is in communication with the outlet, so that only particles having a size effective for inhalation are transported by the air stream to the second, higher level and through the outlet of the mouth tube. The outlet has the shape of a horizontally arranged slit provided in the end face of the mouth tube.

20152-1242D

Inhaler for multiple dosed administration of a pharmacological dry powder

This is a division of our co-pending Canadian Patent Application 2,239,292 dated December 5, 1996.

Area of application of the invention

The invention relates to a dry powder inhaler with dosed administration of a medical preparation upon inhalation by the patient. The dry powder - in loose form or pre-dosed units for dispensing - is contained in a medicament reservoir. The invention concerns the generic type of inhalers in which, upon activation, a defined dose is first of all introduced from the internal medicament reservoir into the inhalation channel by means of a portioning mechanism, and from there the patient draws this defined dose into his airways via a mouthpiece, in a flow of air generated by aspiration.

Inhalation is a proven method of depositing medicinal agents in the lungs or delivering them to the blood. Thus, in addition to the devices for atomizing or nebulizing of liquids, for example by means of air, compressors, ultrasound, liquefied propellant gases (fluorohydrocarbons, fluorochlorinated hydrocarbons), inhalers for pulverulent preparations with dosed portioning were also developed for the purpose of inhalation.

A defining feature of inhalers is that the active substance particles of the medicament are deposited, by inhalation, in a defined dose and particle size (about 1 - 6 μm) either in the central or peripheral lung compartments (topical treatment) or as very small particles by means of absorption in the alveolar region into the blood stream of the patient (systemic treatment).

However, micronized particles with the diameter in question here have extremely poor flow characteristics. This problem

is solved by a number of conventional methods. Thus, powder mixtures are produced with a carrier which generally has a greater particle diameter than the active substance, with the active substance particles depositing themselves on the carrier surface. On the other hand, in the manufacture of soft pellets, a large number of active substance particles are massed together to form respectively larger particles, the pellets. Under the effect of force, the pellets split up again into the individual, smaller active substance particles. During inhalation it should be possible with the inhaler to detach the active substance particles from the carrier or to break the pellets up again into small particles. Simple swallowing of the medicament is completely undesirable. For this reason, special functional demands are imposed on inhalers in principle.

Prior art

EP application number 90306537.3 published on December 27, 1990 and EP application number 92850046.1 published on March 4, 1992 disclose inhalers for single use. Such designs are appropriate only for special applications, since on the one hand the patient has no control over the correct use, i.e. the optimum inhalation, and on the other hand a new inhaler has to be used for each inhalation, which is costly, inconvenient and not environmentally friendly.

Thus, inhalers with a dry powder as medicament were developed also for multiple use. PCT International application number PCT/CH92/00164 published on March 4, 1993 as International Publication Number WO 93/03782 discloses an inhaler with a medicament reservoir and a dosing mechanism, by means of which the medicament is conveyed in doses from the storage container into the inhalation channel and can be sucked from there with the flow of air generated by the

patient. This inhaler does not yet satisfy all the requirements. The exact and prescribed use can still not necessarily be sufficiently guaranteed. The dosing accuracy has to be increased; humidity too easily penetrates into the inhaler, the deagglomeration and atomization have to be improved, and keeping the inhaler clean is complicated.

U.S. Patent No. 5,239,992 discloses a further inhaler in which a dosing cavity is present in a longitudinally displaceable piston rod and this dosing cavity, first positioned under the medicament reservoir, receives a dose of medicament. The patient has to inhale counter to the force of a spring, so that the piston rod moves and the ready-to-use dose can be sucked by the patient through suction openings in the guide channel of the piston rod. In principle, this inhaler too exhibits the abovementioned inadequacies.

PCT International application number PCT/GB93/01893 published on March 17, 1994 as International Publication Number WO 94/05359 describes an inhaler for multiple dosed administration of a pharmacological dry powder which is contained within a medicament reservoir provided inside the housing. On the inhaler a mouthpiece is joined which is closed outside inhalations by a folding down protective cap. The inhaler further has inside a horizontally movable carriage with a dosing depression. If the protective cap is closed the dosing depression is positioned underneath the funnel-shaped outlet of the medicament reservoir, so that dry powder by its gravity should flow into the dosing depression until it is full if the inhaler is in a vertical position. One filling of the depression represents one dose.

After a preceding inhalation a spring arranged above a bellows is tensed by closing the protective cap. The bellows is placed on the medicament reservoir, an air permeable membrane is provided as a separating wall. During opening the protective cap the locking of the tensed spring is released, so an air pressure pulse acts upon the medicament reservoir. This air pressure pulse ought to guarantee that in each case the dosing depression is properly filled with dry powder. The carriage is moved by further opening of the protective

cap, so the dosing depression is positioned within a suction channel. With the inhalation the medicament dose is sucked out from the dosing depression through the mouthpiece.

The mouthpiece has at one side a flange for joining to the housing of the inhaler and has at the other side a suction pipe outwardly trumped-like opening. A flow channel flows tangentially into the flange which channel is connected with the suction channel, where the medicament dose is available in readiness for inhalation. At the flange tangentially arranged air openings are provided for the purpose of turbulence of the medicament containing air stream sucked into the mouthpiece.

The spring above the bellows again tenses by closing the protection cap and the carriage goes back into its starting position, so the dosing depression is again positioned underneath the funnel-like outlet of the medicament reservoir and the next inhalation cycle can start.

The previously described inhaler and its pertinent mouthpiece shows the following essential disadvantages:

- Independent of the intensity of the inhalation the medicament from the dosing depression can be sucked out too low that the medicament particles only insufficiently arrive at their intended position within the patient's respiratory ducts and/or actually only a part of the dose available is sucked out. Thus the patient has no control as to whether the inhalation has been actually done or correctly completed.

- After opening of the protective cap and during inhalation the inhaler has to be positioned vertically, otherwise the dry powder can from the dosing depression flow back into the medicament reservoir or come into the suction channel

situated above the dosing depression and deposit there as a loss. A construction feature is missing which obliques the patient to apply the inhaler in the right functional position.

- At least a part of the dry powder of the unused dose can come into the suction channel if the inhalation is incompletely finished or not done at all and the inhaler is not held strictly vertically. By the next inhalation cycle it is metered again, therefore inaccuracies of the dosage can emerge. Based on the construction double dosages or dosages under the limit can happen.

- The extending bellows sucks in a larger amount of external air with each closing of the protective cap, their moisture can arrive successively into the medicament reservoir. This is disadvantageous for the flowability and the accuracy of metering of the dry powder as known from the literature and the practice.

- A further construction feature is missing which guarantees that the last 5 to 10 nominal doses in the declared measure (weight and volume) can be delivered in order to solve the tail-off-problem known of inhalers with a multi dosage reservoir.

- The mouthpiece has at its flange a tangentially discharging channel and openings for acceleration and turbulence of the airstream generated by the patient. This corresponds with the cyclone principle as used for a long time for the dry powder inhalers available on the market (e.g. Spinhaler®, Cyclonhaler®).

- The unit of turbulence and the mouthpiece can be cleaned and dried internally relatively ill which under circumstances can cause microbiological problems.

Object of the invention

Thus, in summary, it may be stated that none of the inhalers known to date can be regarded as optimal. The invention is therefore based on the problem of producing an inhaler whose functional characteristics are extensively improved. The design construction is intended to conclusively guarantee the prescribed inhalation position and inhalation intensity. In the inhaler there must be a suitable registration and function covering a properly completed inhalation, an omitted inhalation, or an incomplete inhalation; in any event, a multiple dosage is to be prevented. It is necessary to improve the dosing accuracy upon preparation of the individual doses from the medicament reservoir, and the deagglomeration and atomization of the medicament during inhalation. The protection against humidity is to be made more effective and the cleaning of the inhaler should be made easier. It must be ensured that a mouthpiece which has been removed for cleaning is fitted in place again by the patient. The mouthpiece ought to be used as well as in connection with the inhaler to be created as with other inhalers of the present type. Finally, it must be possible for the inhaler to be manufactured efficiently as a mass-produced article and at the same time satisfy all the regulations laid down in drugs legislation.

Summary of the invention

The inhaler is used for the multiple dosed administration of a pharmacological dry powder; it consists externally of a housing and of a protective cap which can be removed from a special mouthpiece fitted on the housing. Arranged on the inside there are a slide rail, a dosing slide, a shutter, a carriage, a funnel arrangement, a counter device, a valve shield and a valve guide. Removal of the protective cap initiates the dosing, with the dose received in the dosing cavity being transported to the mouthpiece by means of the dos-

ing slide. Only upon application of a defined minimum intensity of inhalation is the shutter moved by the suctioned valve plate, as a result of which the dose is released for inhalation. Only after properly completed inhalation can the dosing slide be returned with its dosing cavity under the funnel outlet for the purpose of preparing for renewed filling.

In the inside of the inhaler there are blocking means which come into action as soon as the inhaler, upon removal of the protective cap, is situated in a horizontal and/or axial inclined position going beyond a defined extent. The correct dosing and use position of the inhaler are guaranteed in this way. For the patient's safety, optional blocking means can be fitted which prevent any possibility of the protective cap of the inhaler being closed when the mouthpiece is missing. This ensures that after the mouthpiece has been removed, it is not possible to omit to replace it.

According to a broad aspect of the invention, there is a mouthpiece for an inhaler, comprising: a channel inlet; a mouth tube having an end face with an upper portion and a channel outlet located in said upper portion of said end face; and an atomizer path extending within said mouth tube from said channel inlet to said channel outlet, said atomizer path including a first channel section and a second channel section, said first channel section having at least one baffle and being in communication with said channel inlet and located at a first level, said second channel section being in communication with said first channel section and said channel outlet, said second channel section including a first portion located at said first level, said first portion communicating with said first channel section and having a larger volume than said first channel section

and a second portion located at a second level which is higher than said first level, said second portion being in communication with said channel outlet of said mouth tube, and said channel outlet including a horizontally oriented slit located in said upper portion of said end face of said mouth tube.

In the inhaler there are means which contribute to the regular flow of the pharmacological dry powder when the protective cap is removed. The generated vibrations preferably only exert an effect while the dosing cavity is located under the funnel outlet. These means are advantageously complementary grate sections which are located on components moved relative to one another.

The inhaler can be supplemented with an electronic module and a controllable nozzle so that all data relevant to inhalation can be recorded and the flow conditions regulated. Completion of a correct inhalation, or an incomplete inhalation, can be indicated by an acoustic and/or optical signal.

Brief description of the attached drawings

Figure 1A inhaler, side view; closed state (starting position → situation A1);
Figure 1B inhaler, rear view;
Figure 1C inhaler, front view;
Figure 1D inhaler, plan view;
Figure 1E inhaler: protective cap pulled out (intermediate position → situation A2)
Figure 1F inhaler: protective cap swung down fully (ready for inhalation → situation A4; inhalation omitted → situation A5; inhalation incomplete → situation A6; inhalation complete → Situation A7);

Figure 2A protective cap, perspective view;
Figure 2B protective cap, plan view;
Figure 2C protective cap, side view;
Figure 2D view into the protective cap;

Figure 3A lower part of housing, perspective view;
Figure 3B lower part of housing, plan view;
Figure 3C lower part of housing, side view;
Figure 3D lower part of housing, cross-sectional view;

Figure 3E lower part of housing, perspective view with blocking hooks and balls;

Figure 3F lower part of housing according to Figure 3E, plan view;

Figure 4 upper part of housing, perspective view;

Figure 5A mouthpiece, perspective view of the base plate;

Figure 5B mouthpiece, side perspective;

Figure 5C one half of mouthpiece, external view;

Figure 5D one half of mouthpiece, internal perspective;

Figure 5E mouthpiece opened out, internal perspective;

Figure 6A slide rail, perspective view from below;

Figure 6B slide rail, side perspective;

Figure 7A carriage, perspective view from below;

Figure 7B carriage, perspective view from above, laterally, from the front;

Figure 7C carriage, perspective view from above, front;

Figure 7D carriage, perspective view from above, rear;

Figure 8A dosing slide, perspective view from above;

Figure 8B dosing slide, perspective view from above, rear;

Figure 8C dosing slide, perspective view from below;

Figure 9A shutter, perspective view from above;

Figure 9B shutter, perspective view from below;

Figure 10A valve shield, perspective view;

Figure 10B valve shield, side perspective;

Figure 11A valve guide, inner perspective;

Figure 11B valve guide, outer perspective;

Figure 12A funnel, perspective view from above;

Figure 12B funnel, perspective view from below;

Figure 13A funnel holder, perspective view from above;

Figure 13B funnel holder, side perspective;

Figure 13C funnel holder, perspective view from below;

Figure 14A funnel lid, perspective view from above;
Figure 14B funnel lid, perspective view from below;
Figure 14C funnel lid with semi-permeable membrane;

Figure 15A funnel holder, funnel and funnel lid, side perspective;
Figure 15B funnel holder and fitted funnel, perspective view from above;

Figure 16A counter, perspective view of the units wheel;
Figure 16B counter, perspective view of the hundreds wheel;
Figure 16C counter, units wheel, outer perspective;
Figure 16D counter, units wheel, inner perspective;
Figure 16E counter, tens wheel, outer perspective;
Figure 16F counter, tens wheel, inner perspective;
Figure 16G counter, hundreds wheel, inner perspective;
Figure 16H counter, hundreds wheel, outer perspective;
Figure 16I counter body, inner perspective;
Figure 16J counter body, outer perspective;
Figure 16K counter, cover plate, outer perspective;
Figure 16L counter, cover plate, inner perspective;
Figure 16M counter, drive wheel, outer perspective;
Figure 16N counter, drive wheel, inner perspective;
Figure 16O engagement of the dosing slide on the counter, units wheel;

Figure 17A blocking hook, plan view;
Figure 17B blocking hook, perspective view from right;
Figure 17C blocking hook, perspective view from left;

Figure 18A inhaler, horizontal longitudinal section according to Figure 1A on line A-A;
Figure 18B inhaler, vertical longitudinal section according to Figure 1D on line B-B;
Figure 18C inhaler, vertical transverse section according to Figure 1D on line C-C;

Figures 19A to 19D functioning principle of the release of the shutter;
Figure 19A side wings of the carriage with aperture and cam;

Figure 19B closed inhaler according to Figures 1A and 18A (situation A1);

Figure 19C shutter close to release, with the protective cap not swung down fully (situation A3);

Figure 19D shutter released, with protective cap swung down fully in accordance with Figure 1F (situation A4);

Figures 20A to 20F functioning principle of the inhaler

Figure 20A inhaler closed in accordance with Figures 1A, 18A and 19B (starting position → situation A1);

Figure 20B inhaler open in accordance with Figures 1F and 19D (ready for inhalation → situation A4);

Figure 20C closing the inhaler (inhalation omitted → situation A5);

Figure 20D closing the inhaler (inhalation incomplete → situation A6);

Figure 20E inhaler closed (after incomplete inhalation → situation A8);

Figure 20F inhaler closed (after completed inhalation → situation A7);

Figures 21A to 21C functioning principle of the blocking hooks:

Figure 21A blocking hooks fitted (starting position → situation B1);

Figure 21B protective cap blocked when mouthpiece missing (incorrect position → situation B2);

Figure 21C pivotable protective cap, with mouthpiece fitted (desired position → situation B3);

Figures 22A and 22B functioning principle of the blocking of the inhaler at an inclined position:

Figure 22A side position of the blocking balls on incorrect positioning of the inhaler;

Figure 22B blocked inhaler;

Figures 23A to 23G successive construction of inhaler, perspective views;

Figure 23A lower part of housing with valve shield, valve guide and one mouthpiece half;

Figure 23B representation in accordance with Figure 23A, with slide rail and carriage added;

Figure 23C representation according to Figure 23B, with dosing slide added;

Figure 23D representation in accordance with Figure 23C, with shutter added;

Figure 23E representation in accordance with Figure 23D, with protective cap added, without lower part of housing;

Figure 23F representation in accordance with Figure 23E, with funnel holder, funnel, funnel lid and counter added; and

Figure 23G representation in accordance with Figure 23F, from the rear side.

Exemplary embodiment

In the text which follows, the inhaler according to the invention will be described in greater detail in terms of its construction, as well as its function, with reference to the attached drawings, and possible modifications are mentioned by way of conclusion.

The following statement applies to the whole of the description following. If, for the purpose of clarity of the drawing, reference numbers are included in a figure but are not explained in the directly relevant text of the description, then reference is made to their mention in preceding figure descriptions. In the interest of intelligibility, the repeated designation of components in succeeding figures is for the most part omitted if it is clear from the drawings that the components concerned are "recurring" components.

Figures 1A to 1D

Externally, the inhaler according to the invention is made up of the lower part **100** of the housing, the upper part **150**

of the housing, and the protective cap **950**. The lower part **100** of the housing and the upper part **150** of the housing have an elongate, semi-monocoque configuration. The upper part has, on its top side, a fairly large opening **151** for receiving a funnel lid **680**, and a window **152** through which the status of the counter can be read off. The lower part **100** of the housing and the upper part **150** of the housing are joined to one another such that a housing is obtained which is in principle closed. Grip contours **951** are provided on the outside of the protective cap **950** to permit better gripping. Grip contours, preferably designed as grip dimples **113**, are also arranged on both sides of the housing, in this case extending over the lower part **100** of the housing and the upper part **150** of the housing.

On the top of the protective cap **950**, towards the outer edge, there is an elongate recess, by which means a clearance **968** is created together with the adjoining upper part **150** of the housing. By looking into this clearance **968** it is possible to ascertain if the mouthpiece is fitted and the clearance **968** is thus filled, or if the mouthpiece is missing and the clearance **968** is consequently open. Opposite the protective cap **950** - on the rear part of the inhaler - the perforated base **854** of the valve guide enclosed by the lower part **100** of the housing and upper part **150** of the housing can be seen.

In the closed state shown here, the starting position - subsequently referred to as *Situation A1* - the protective cap **950** is fitted flush with the lower part **100** of the housing and the upper part **150** of the housing. Thus, the medical preparation stored in the inhaler is protected quasi hermetically from external humidity.

Figure 1E

The inhaler has to be opened before use; to do this, the protective cap **950** is first of all pulled out in the axial direction. The line along which the protective cap **950** is pulled out is limited by a pair of side arms **960** which are fixed on the protective cap **950** and engage in a longitudinally displaceable manner in the inside of the inhaler. With the protective cap **950** pulled out this far, the mouthpiece **900** is already partly visible, which mouthpiece is attached to the lower part **100** of the housing and the upper part **150** of the housing at the front and is enclosed on both sides by the side arms **960**. As will be explained later, this step is associated with a temporary vibration for exact dosing of the medicament from the powder reservoir. This intermediate position, with the protective cap **950** pulled out, is hereinafter referred to as *situation A2*.

Figure 1F

In order to allow the patient access to the mouthpiece **900**, i.e. to permit inhalation, the protective cap **950** suspended on the side arms **960** has to be swung down in a further maneuver. The mouthpiece **900** with the mouth tube **920** protruding from the base plate **910** is now fully visible. The channel outlet **922** through which the patient inhales the medicament is situated on the end face **921** of the mouth tube **920**.

In this position, with the protective cap pulled out and swung fully down - subsequently referred to as *Situation A4* - the inhaler itself is prepared for inhalation. The dose of medicament which has been made ready is in a loosened state. It should be understood that the protective cap **950** can only be swung down when it has first been pulled out to the limit. The dimensioning of the mouthpiece **900**, the length of the side

arms **960**, and the sole possibility of swinging the protective cap **950** downwards, cause the patient by necessity to place the inhaler in the correct position. If the inhaler were used upside down in error, the patient would notice this immediately since his nose would hit against the protective cap **950** and he would thus barely be able to apply the mouthpiece **900**.

Situation A3 characterizes the state in which the protective cap **950** is in its swing movement and has not yet reached its lowest position.

Figures 2A to 2D

The protective cap **950** consists of the two aforementioned side arms **960** and the actual cap **952**. The clearances **968**, which provide space for the base plate **910** of the mouthpiece **900**, are arranged on that edge of the cap **952** facing towards the mouthpiece **900**, centrally on the top side and bottom side.

The two side arms **960** each extend laterally into the cap **952**. At the front part, which engages in the inhaler, the side arms **960** have a special construction symmetrical to one another. Each side arm **960** has a square, rounded aperture **961**, a pin **962** lying below the latter and directed inwards, a recess **963** incorporated from the underside of the side arm and having a cut edge **964**, as well as forward bevels **969**. Between the aperture **961** and the cut edge **964** in each side arm **960** there is a further rectangular aperture **970**. Offset above this aperture **970** there is an outwardly directed dimple **971**. The same type of dimple **972** is arranged in the lower area of the side arm **960** near the entry to the cap **952**.

Figures 3A to 3D

The lower part **100** of the housing has, on both sides, a plurality of stop cams **101** spaced apart from one another and projecting above the side wall. To the rear, the lower part **100** of the housing is strengthened at the end, so that a semicircular bearing ring **102** is obtained. A double wall **103**, likewise semicircular and with a radial receiving groove **104**, is provided on the base at a distance from the bearing ring **102**. Running centrally between the double wall **103** is a raised, axial connecting web **115**.

Arranged on the base are two parallel bars **106** which extend from the front side **105** and which each have an outwardly facing indentation **116** in the rear area and an obliquely cut aperture **117** in the front area. Together with two columns **118** lying opposite one another at a distance, and a rail **119** extending along the wall of the lower part **100** of the housing, the indentation **116** delimits a depression-like ball socket **108**. There is also an indentation **120** provided in the rail **119**, and the indentations **116,120** of identical form lie opposite one another. The columns **118** have points **121** which are directed towards one another and which at their deepest point are located in the ball socket **108**. On each of the rear columns **118** there is an inwardly pointing hook **122**. A raised plug **123** is in each case arranged in front of the front pillars **118**, facing towards the front side **105**. At the said front side **105**, two receiving notches **109** are incorporated, as well as two axially extending longitudinal slots **110** in the base - near each housing wall. A safety cam **125** sits to the side at the entrance of each longitudinal slot **110**. Between the two bars **106** and the front side **105** there are two U-shaped depressions **124**.

Figures 3E and 3F

In the completed state, a blocking ball **130** lies in each ball socket **108** and, with the inhaler in the correct position, this blocking ball **130** is located at the deepest point between the points **121** of the columns **118**. When the inhaler is in an excessively horizontal or axial inclined position, the blocking balls **130** roll into the indentation **116** of the bar **106** or into the indentation **120** of the rail **119** and effect a blocking of the inhaler, as described in Figures 22A and 22B.

To ensure that the removed mouthpiece **900** is put back in place before the inhaler is closed, blocking hooks **140** are optionally fitted on the plugs **123**. A blocking hook **140** consists of a spring arm **142** and a lever **143** with a laterally protruding blocking tooth **144** and the catch **145** pointing to the front side **105**. The spring arm **142** of a blocking hook **140** passes through the aperture **117**, while the lever **143** is pressed outwards by the tensioning of the spring arm **142**, so that its blocking tooth **144** protrudes into the course of the longitudinal slot **110** where, in the completed state, the respective side arm **960** of the protective cap **900** sits. The function of the blocking hooks **140** is described in detail in Figures 21A to 21C.

Figure 4

Complementing the stop cams **101**, the upper part **150** of the housing has plug holes **153** on its side walls. Analogously to the lower part **100** of the housing, the upper part **150** of the housing also has a semicircular bearing ring **154** to the rear, as well as a double wall **155** with a receiving groove **156**. The half bearing rings **102** and 154, respectively, and

the receiving grooves **104** and **156** combine to form full circles.

On the side walls, mounted ahead of the receiving groove **156**, there are in each case a support cam **158** and a higher overspring rib **157**. The support cam **158** and the overspring rib **157** project towards the center of the upper part **150** of the housing and have a common point of origin on the side wall. Adjacent to the window **152**, two parallel supports **159** spaced apart from one another are arranged on the housing bottom. In the bottom there is also the recess **151** for the funnel which is to be fitted. On both sides of this recess **151**, towards the side walls, a limit cam **164** in each case stands out from the bottom of the housing.

Corresponding to the longitudinal slots **110** in the lower part **100** of the housing, there are also two slots **161** in the front side **160** of the upper part **150** of the housing. In the front side **160** there is additionally a central receiving notch **162**, and two elastic clamping prongs **163** extend from the front side **160** in the direction of the mouthpiece **900**. A cross-piece **165** stretches between the front side **160** and the base of the clamping prongs **163**, and adjacent to the receiving notch **162**. To the rear of the front side **160**, the clamping prongs **163** merge into a vertical U-profile **166**, the vertical grooves **167** of the U-profiles **166** internally adjoining the front side **160** and facing one another.

Figures 5A to 5E

The mouthpiece **900** consisting of the base plate **910** and the mouth tube **920** is advantageously made of two halves which are joined together, for example, by an integral film hinge **923** provided on the end face **921**. On the base plate **910**,

facing the inhaler, there is a full connector plug **911** at the bottom of each half, and a half-cam **912** at the top, which complements the adjacent half- cam **912**. Each connector plug **911** has at its front free end, in the lower area, a recess **930** with an inwardly directed bevel **931**.

Incorporated underneath the two half-cams **912** is an engagement opening **913** which extends as a shaft **932** right into the mouth tube **920**. Deeper in the shaft **932**, a recessed groove **933** is present in each case laterally in the wall of the mouth tube **920**. The channel inlet **914** for the atomizer path **924** of the mouth tube **920** lies below the engagement opening **913**. The channel inlet **914** is connected to the channel outlet **922** via the atomizer path **924**. A horizontal ramp **935**, complementing the second half of the mouthpiece, is in each case arranged on the base plate **910** under the channel inlet **914**.

Inside the atomizer path **924**, behind the channel inlet **914**, there are a plurality of baffles **925** which protrude into the atomizer path **924** for impacting the medicament-containing air stream and causing it to swirl, so that the atomizer path **924** acquires a course which is rich in curves. Nearer the channel outlet **922**, the powder aerosol flowing through enters via an S-curve into an enlarged channel section **928** and is here deflected to the channel outlet **922**. The purpose of the special configuration of the atomizer path is to deagglomerate the powder and to reduce the flow rate of the powder so as to deposit coarser particles which are ineffective for inhalation. At the same time, the impacting of particles of active substance in the pharynx of the patient is thus prevented. The mouth tube **920** is flattened off horizontally, at least in the area of the end face **921**, so that the

patient is induced to employ the correct positioning of the inhaler during use.

Figures 6A and 6B

The slide rail **200** has two longitudinal grooves **202** which extend laterally from the end face **201** and parallel to one another, and which reach to approximately halfway along the slide rail **200**. In a continuation of the end face **201**, two feet **204** spaced apart from one another extend downwards from the bottom of the slide rail **200**. At the top, the slide rail **200** has a ledge-like roof part **210** which protrudes over the end face **201** in the manner of a projecting roof. At the opposite end from the end face **201**, the slide rail **200** ends in a sloping surface **205** which merges ramp-like with the top surface of the slide rail **200**, the roof part **210** ending in front of the sloping surface **205**.

Figures 7A to 7D

The carriage **500** has two wings **503,523** rising laterally and beginning on the front side **501**, with an outwardly directed cam **504** being in each case arranged thereon. The cam **504** is wider in the horizontal than in the vertical, so that an approximately oval shape is obtained. An arcuate aperture 505 is incorporated in the wings **503,523** and runs round the cam **504** from below in a part circle. At its rear side **507**, the carriage **500** has two laterally rising struts **508,510**, the strut **508** having a horizontal shoulder **509**. Two pull cams **512** rise from the carriage base **511**, while to the rear side **507** the carriage base **511** continues in the form of two elastic spring tongues **513** which end as spring wedges **514** and can be deflected out to the sides. Between the two spring tongues **513**, a longitudinal groove **520** extends centrally through the carriage base **511**. A pull catch **521** is present

on the front side **501** between the groove **520** and each of the wings **503,523.** Towards the front side **501,** the wing **523** has a grate section **515** on the inside.

Underneath the groove **520,** the carriage **500** has two runners **522** on its underside. Also on the underside of the carriage, towards the outside as viewed from the runners **522,** there are two pairs of impact ridges **524** which correspond to the two ball sockets **108** in the lower part **100** of the housing. The two impact ridges **524** of one pair are arranged at a distance from one another. A stepped bulge **516** is positioned ahead of each pair of impact ridges **524,** in the direction of the front side **501.**

Figures 8A to 8C

Near its front edge **301,** the tongue-like dosing slide **300** has a through-bore, the dosing cavity **302.** Starting from the front edge **301,** the dosing slide **300** extends firstly as a narrow tongue tip **303** and then widens to the rear part 304. A spring leaf **305,** from which a cam **306** rises, is arranged on the outside flank of the rear part **304.**

On the underside, the dosing slide **300** has flank ridges **307** which begin immediately behind the dosing cavity **302** and there form limit stop edges **308.** The dosing cavity **302** is surrounded by a radial sealing rim **320** on the underside. Near the transition to the rear part **304,** there are two downwardly extending transverse cams **309.** On the rear edge **310** of the dosing slide **300** there are two downwardly directed, profiled catches **321.**

Figures 9A and 9B

The shutter **400** has the function of releasing the medicament made ready in the dosing cavity **302** only when there is a suitably forceful inhalation. At the very front, the shutter **400** has a sleeve-like closure part **401** with the through-opening **402**. Behind the closure part **401** there are outer, vertical side ridges **403**, beginning with a limit stop **404**. An outwardly directed and ramp-shaped wing **405** is arranged on each side ridge **403**. In the direction of the rear part **406**, the wing **405** is followed by a side bracket **407**. At the bottom, on the rear edge **408**, the shutter **400** also has an outwardly directed carrier **409**. On the bottom, in the area of the wings **405**, two base plates **410** extend towards one another, leaving a through-gap **411**. Towards the rear edge **408**, the end of the rear part **406** is provided with a cover **420** which at the top stretches across the two parallel side ridges **403** and begins approximately in the area of the side brackets **407**. In the cover **420** there is a rounded-off groove **421** which extends along the middle and which is open to the center of the shutter **400**.

Figures 10A and 10B

The valve shield **800** has the function of inducing the patient to generate a defined minimum suction for a correct inhalation. The valve shield **800** consists of a cylindrical capsule **810** and a plurality of arms attached thereto and having different tasks. The capsule **810** has a flange-like collar **811** surrounding the opening and protruding outwards. The bottom **812** of the capsule **810** is convexly curved outwards and has a large number of raised studs **813** on the outside.

The further elements of the valve shield **800** are attached perpendicularly onto this collar **811** and in the axial direction. On the collar **811** there is firstly a pair of long tentacles **820** which lie opposite one another and which have carriers **821** at their very front. Before the tentacles **820** there are two shorter spring arms **822** with outwardly directed wedge profiles **823** at their tips. Behind the tentacles **820** there are two further spring arms **825** with outwardly directed hooks **826**. Between these spring arms **825** there are two short locking teeth **824** standing close to one another.

Figures 11A and 11B

The capsule-shaped valve guide **850**, when fitted into the lower part **100** of the housing and the upper part **150** of the housing, serves to receive the valve shield **800**, i.e. its capsule **810**. To this extent the valve guide **850** has the function of a slide bearing. Complementing the collar **811** of the valve shield **800**, the valve guide **850** has an external limit stop flange **851**. Slide ribs **852** in the inside of the valve guide **850** have the purpose of reducing the friction as the valve shield **800** travels out. The perforated bottom **854** has numerous holes **855**, so that the stubs **813** of the valve shield **800** find space therein. At the top and bottom of the limit stop flange **851** there are two diametrically opposite notches **856**. The holes **855** and the stubs **813** make it possible to design the inhaler virtually closed at the rear and thus to prevent the penetration of dirt particles and the inadvertent displacement of the valve shield **800**.

Figures 12A and 12B

The funnel **690** is intended for fitting into the funnel holder **601** (see Figures 13A,13B). The funnel bottom **691** is

designed sloping obliquely towards the outlet **692**, so that the medicament powder flows in a favorable manner. The outlet **692** is surrounded on the outside by a sealing element **694**. On the outside, the funnel **690** has retainer cams **695** projecting upwards on two opposite sides, as well as a centrally positioned fixing nose **696** which sits on the oblique funnel bottom between the retainer cams **695**.

Figures 13A and 13B

The box-shaped funnel holder **601** has, on the underside, the holder bottom **603**, the front wall **611**, the rear wall **612**, and the two half-height side walls **613,614** lying between the front and rear walls **611,612**. Located in the holder bottom **603** are the funnel outlet **608** and an elongate groove **615**. At the very bottom, a sealing member **622** surrounds the funnel outlet **608**, so that it is possible to prevent the entry of humidity and the escape of powder from the funnel **690** onto the sliding surfaces of the dosing slide **300**.

Arranged perpendicularly on the front wall **611** are two angled rails **616**, and at the top of the rear wall **612** there is a support edge **602**, from which a spring arm **617** in each case extends along the two side walls **613,614**. A groove **618** facing the respective side wall **613, 614** is provided in each of the spring arms **617**. The side walls **613,614** each have a downwardly open notch **619** approximately at their center on the lower edge. A grate section **621** is provided on one side wall **613** near the rear wall **612**. Two elastic lamellae **605** opening in the rear wall **612** extend along the outer flanks of the holder bottom **603**, at the vertically movable ends of which lamellae **605** there are downwardly projecting blocking cams **609**.

Figures 14A to 14C

The funnel lid **680** serves to close the funnel **690.** On the underside of the funnel lid **680** there is a chamber **681** which is closed by a semi-permeable membrane **682**. The chamber **681** is intended to receive a moisture-attracting desiccant powder and the moisture can diffuse through the semi-permeable membrane **682.**

Figures 15A and 15B

When the funnel arrangement is in its completed state, the funnel **690** is fitted into the funnel holder **601**, and the funnel **690** is closed by the funnel lid **680**. However, the sequence of assembly of the inhaler need not include the prior completion of the funnel arrangement.

Figures 16A and 16B

The complete counter 700 consists of the units wheel 701, the tens wheel **780**, the hundreds wheel **720**, the counter body **740**, the counter cover plate **760**, and two identical drive wheels, which are not shown here. The purpose of the counter **700** is to register the number of doses used or doses still available and to indicate to the patient the inhalation which has just taken place, as long as it was performed correctly. Numbers and, if appropriate, a color marking are provided on the circumference of the counter wheels **701,780** and **720** fixed on the axle **741** of the counter body **740.** The current status of the counter is displayed under a lens **742** which sits in the window **152** of the upper part **150** of the housing. The lens **742** is connected to the counter body **740.**

Figures 16C and 16D

The units wheel **701** has ten radially distributed cams **703** on its outer surface **702.**

Figures 16E and 16F

The tens wheel **780** with its inner toothed ring **781** is itself of a conventional construction.

Figures 16G and 16H

The hundreds wheel **720** likewise has an inner toothed ring **721** and an outwardly protruding end cam **722**.

Figures 16I and 16J

The counter body **740** consists of the base plate **743**, the lens **742** set on the top at right angles, the axle **741** extending perpendicularly from the base plate **743**, as well as the drive-wheel bearing **744**.

Figures 16K and 16L

Bearing on the units wheel **701**, the counter cover plate **760** is fixed on the axle **741** of the counter body **740**. The counter cover plate **760** has an elastic adjusting tongue **761** with a wedge cam **762** at the end, which cam **762** moves at all times between two cams **703** of the units wheel **701**.

Figures 16M and 16N

The star-shaped drive wheel **790** is fitted on the one hand between the units wheel **701** and the tens wheel **780** and on the other hand between the tens wheel **780** and the hundreds wheel **720**. It has six uniformly arranged teeth **791**, of which every second tooth **791** has an undercut **792** at its tip on one side of the drive wheel **790**.

Figure 16O

When a correct inhalation has been completed and the inhaler has been closed again by swinging the protective cap **950** upwards and pushing it in, the actuation of the counter **700**

takes place. Only on pushing the dosing slide **300** back into the starting position - *Situation A1* - is a cam **703** on the units wheel **701** gripped by the cam **306** situated on the spring leaf **305**, and the units wheel **701** thereby turned by one count position.

When the intended number of doses have been taken from the inhaler, the hundreds wheel **720** is in such a position that the end cam **722** has positioned itself at the far top and, on pulling the carriage **500** out, the shoulder **509** (see Figures 7A to 7D) strikes against the end cam **722**. Further actuation of the inhaler is thus blocked.

Figures 17A to 17C

As an option for increasing the safety of handling of the inhaler, two rotationally movable blocking hooks **140** are provided which can be fastened onto the plugs **123** in the lower part **100** of the housing. The blocking hook **140** is two-armed and is divided into a thin spring arm **142** and a more solid lever **143**, the spring arm **142** spreading away from the lever **143**. The blocking hook **140** has a bore 146 so that the blocking hook **140** can be fastened onto the plug **123**. On the lever **143** there is a blocking tooth **144** protruding out to one side and pointing away from the spring arm **142**, as well as a catch **145** pointing forwards and extending the length of the lever **143**.

Figures 18A to 18C

In the assembled state, the following arrangement obtains in *Situation A1*. The lower part **100** of the housing and the upper part **150** of the housing are joined together. The mouthpiece **900** is inserted from the front and the protective cap **950** is fully closed.

The slide rail **200**, the carriage **500**, the dosing slide **300**, the shutter **400** lie in the housing parts **100,150**. The valve guide **850** is fitted, and therein the valve shield **800**, as well as the complete funnel arrangement - consisting of funnel **690**, funnel holder **601** and funnel lid **680** - and the counter **700**. The valve shield **800** is in its rearmost position, and the dosing slide **300** is located such that the dosing cavity **302**, positioned under the funnel outlet **608**, can fill with medicament. The closure part **401** of the shutter **400** protrudes into the channel inlet **914**. The clamping prongs **163** - additionally fixing the mouthpiece **900** - sit in its shaft **932** and engage in the grooves **933**. The half-cams **912** of the mouthpiece **900**, joined together, are locked in the receiving notch **162** in the upper part **150** of the housing. The connector plugs **911** of the mouthpiece **900** pass through the receiving notches **109** in the lower part **100** of the housing, and the ramp **935** of the mouthpiece **900** engages under the front edge of the roof part of the slide rail **200**. The side arms **960** of the protective cap **950** protrude through the slots **110,161** in the lower part **100** of the housing and in the upper part **150** of the housing and embrace the wings **503,523** of the carriage **500**. The pins **962** now hang in the apertures **505**, while the cams **504** engage in the apertures **961**. To fix the protective cap **950** in the starting position, the safety cams **125** are locked into the dimples **972**.

The feet **204** of the slide rail **200** engage in the depressions **124** in the lower part **100** of the housing. The angled rails **616** of the funnel holder **601** are driven into the vertical grooves **167** of the U-profiles **166** on the upper part **150** of the housing. The funnel **690** sits with its retainer cams **695** and its fixing nose **696** in the notches **619** and in the groove **615**, respectively, of the funnel holder **601**. The outlet **692** of the funnel **690** with the sealing member **694** is situated in the funnel outlet **608**. In addition, the funnel holder **601** is fixed laterally by the limit cams **164** in the upper part **150** of the housing.

The complete counter **700** is held by the supports **159** in the upper part **150** of the housing. The capsule **810** of the valve shield **800** sits to the maximum extent in the valve guide **850**, the limit stop flange **851** of the latter sitting in the receiving grooves **104,156** of the lower part **100** of the housing and the upper part **150** of the housing, respectively, and the connecting web **115** coming into engagement with the notch 856.

Figures 19A to 19D

This sequence of figures illustrates the release of the shutter **400** which surrounds the dosing cavity **302** of the dosing slide **300** filled with medicament, upon swinging the protective cap **950** down.

Figures 19A and 19B

In accordance with *Situation A1*, the carriage **500** is so positioned that its wings **503,523** stand before the funnel holder **601**, i.e. the pin **962** of the side arm **960** of the protective cap **950**, engaging in the aperture **505**, is ineffective as regards unlocking the unmovable shutter **400**. The

blocking cams **609** under the funnel holder **601** engage behind the wings **405** projecting laterally on the shutter **400**. The dosing cavity **302** is situated underneath the funnel outlet 608 and could already be filled with medicament.

Figure 19C

The protective cap **950** has in the meantime been pulled out completely and the carriage **500** hanging on the side arms **960** has been pulled forward; *Situation A2* has been reached. The shutter **400** is still unmovable and, with its closure part **401**, surrounds the dosing cavity **302** which has been pushed into the channel inlet **914** of the mouthpiece **900** by means of pulling off the protective cap **950** and filled with medicament.

The swinging-down of the protective cap **950** now commenced, i.e. *situation A3* is being implemented. However, the protective cap **950** has not yet been swung down fully, so that the pin **962** ascends in the aperture **505** during the swinging-down movement and consequently gradually raises and unlocks the lamella **605** arresting the shutter **400**.

Figure 19D

In *situation A3* which has been reached - this also applies to *Situations A4 to A7* - the protective cap **950** has been swung down fully, as a result of which the pin **962** forces the lamella **605** up. The blocking cam **609** is thus disengaged from the wing **405** on the shutter **400**. The shutter **400** is movable, i.e. readiness for inhalation exists in conjunction with *situation A3*. The swung-down protective cap **950** is fixed in this position by the cooperation of the safety cams **125** in the lower part **100** of the housing and the dimples **971** on the side arms **960**.

Figures 20A to 20F

This sequence of figures illustrates a complete inhalation cycle with the mechanical events occurring in the different possible situations.

Figure 20A

In *situation A1*, the valve shield **800**, the carriage **500** and the shutter **400** are located in their rear end position. This is the state of the inhaler after the protective cap **950** is closed following a correctly performed inhalation or prior to the first use. With the protective cap **950** being pushed in, the shutter **400**, the valve shield **800** and the dosing slide **300** have been pushed back into the rear end position by the carriage **500**. The pull catch **521** of the carriage **500** grips the carrier **409** of the shutter **400**. With its spring wedges **514**, the carriage **500** presses against the catches **321** of the dosing slide **300**, the spring wedges **514** being enclosed to the inside by the locking teeth **824**.

The two struts **508,510** of the carriage **500** have pushed the valve shield **800** into its starting position. A cam **703** on the units wheel **701** of the counter **700** has been put forward one unit by the cam **306** on the dosing slide **300**. The dosing cavity **302** is now once again situated underneath the funnel outlet **608**.

Figure 20B

In *situation A4* the inhaler is in a state of readiness for inhalation. By pulling the protective cap **950** out, the valve shield **800** is advanced from the rearmost position. The carriers **821** on the tentacles **820** have been gripped by the wings **503**, **523** and pulled forward slightly, so that the

stubs **813** of the valve shield **800** are removed from the holes **855** of the valve guide **850** and create air gaps. The inhaling patient is able to draw breath through these air gaps if no other air inlets are provided on the inhaler. On pulling the protective cap **950** out, the carriage **500** was moved with its grate section **515** past the grate section **621** of the funnel holder, so that a vibration was generated for promoting the flow of the medicament powder from the funnel **690** into the dosing cavity **302**. The grate sections **515,621** are dimensioned and arranged in such a way that when pulling the protective cap **950** out, vibrations are generated only so long as the dosing cavity **302** is situated under the funnel outlet **608**. When the carriage **500** begins to pull the dosing slide **300** with it, the grate sections **107** and **515** disengage.

The dosing slide **300** was furthermore gripped via the transverse cams **309** by the pull cams **512** of the carriage **500** and moved forwards in the direction of the mouthpiece **900** to such an extent that the dosing cavity **302** is now surrounded by the closure part **401** of the shutter **400**. The shutter **400** is also released, since the blocking cams **609** underneath the funnel holder **601** have lifted from the wings **405** of the shutter **400** as the protective cap **950** swings down. The wedge profiles **823** of the spring arms **822** of the valve shield **800** stand adjacent to the overspring ribs **157** of the upper part **150** of the housing.

Pressure is exerted from above on the spring arms **617** of the funnel holder **601** so that all the components lying below are subjected to a certain amount of surface pressure. This increases the tightness and prevents the escape of medicament powder. After the protective cap **950** has been swung down, the inhaler is in a state of readiness for inhalation, and

the easier mobility of the shutter **400** is now desired. When the side arms **960** are swung down, the surface pressure acting from above is in part compensated, as the pin **962** ascending in the aperture **505** presses against the lamellae **605**. By means of the oval shape of the cam **504** and the geometry of the aperture **961**, the cam **504** has a deliberately greater vertical play in the aperture **961** than its horizontal play. The reduced surface pressure now affords easier mobility of the shutter **400** upon inhalation.

Figure 20C

In *situation A5* - the inhaler is closed again after an omitted inhalation - the valve shield **800** remained in its position, i.e. it was not sucked forwards. When the protective cap **950** is applied, the carriage **500** is pushed back; its spring tongues **513** move away from the catches **321** of the dosing slide **300**. The valve shield **800** is again pushed into its rearmost position by the carriage **500**; the shutter **400** is locked again. The dosing slide **300** remains, however, with its filled dosing cavity **302** in its forward position; it remains there as a result of suitable friction.

Figures 20D

In *situation A6* - inhalation was interrupted when incomplete - the valve shield **800** has not yet reached its forward position, as a result of which the shutter **400** was not yet displaced, and the dose of medicament remained enclosed. When the protective cap **950** is applied and the carriage **500** pushed back, the dosing slide **300** remains with its unemptied dosing cavity **302** at the front. The spring tongues **513** of the carriage **500** strike via the spring wedges **514** against the catches **321** and are thus bent inwards. In this way the spring wedges **514** strike against the locking teeth **824** and thus push the valve

shield **800** back, until the further pushing back of the valve shield **800** by the two struts **508** and **510** of the carriage **500** takes place.

Figure 20E

After incomplete inhalation and reclosing of the inhaler - *situation A8* - the filled dosing slide **300** stands forward, while the valve shield **800** and carriage **500** are again situated in the rear starting position.

Figure 20F

In *situation A7* - after completed inhalation - the protective cap **950** is swung fully down, as a result of which the pins **962** have lifted the lamellae **605** of the funnel holder **601** and the wings **405** of the shutter **400** have been unlocked. During a correct inhalation, the valve shield **800** has been sucked forwards. The spring arms **822** with the wedge profiles **823** have surmounted the overspring ribs **157** in the upper part **150** of the housing as a result of the valve shield **800** moving forwards. The shutter **400** was pushed into its front end position by the advancing valve shield **800**, by which means the dosing cavity **302** became free and the medicament was inhaled by the patient.

During a correct inhalation the valve shield **800** has been sucked forwards, after its spring arms **822** with the wedge profile **823** have surmounted the overspring ribs **157**. It is possible to define the necessary suction effort with the geometry of the wedge profile **823** and of the overspring ribs **157**, and with the elasticity of the spring arms **822**. In the frontmost position of the valve shield **800**, the two elastic spring arms **825** with the hooks **826** arranged thereon are driven behind the hooks **122** arranged in the lower part **100**

of the housing. This prevents the valve shield **800** from automatically sliding back.

During the reverse movement of the carriage **500**, its spring wedges **514** sit clamped between the catches **321** and the locking teeth **824** and cannot therefore escape. As a result, the dosing slide **300** and the valve shield **800** are now pushed back into the starting position - *Situation A1* - by the spring wedges **514** and the struts **508,510**. In so doing, the hooks **826,122** are released from one another.

Figures 21A to 21C

This sequence of figures illustrates the function of the blocking hooks **140** employed in the interaction with the mouthpiece **900** and the side arms **960** of the protective cap **950**.

Figure 21A

In the starting *position B1*, the protective cap **950** is closed, i.e. pushed on; the mouthpiece **900** however is absent when fitting the blocking hooks **140**. The spring arms **142** protrude through the apertures **117** in the bars **106**, support themselves therein and force the levers **143** outwards. The blocking teeth **144** strike the solid side arms **960** of the protective cap **950**.

Figure 21B

Here - in the incorrect *position B2* - the protective cap **950** is pulled out and swung down; the carriage **500** is pulled forward, so that the spring arms **142** are pressed back into the apertures **117** by the carriage **500**, as a result of which the levers **143** are under increased tensioning. The mouthpiece **900** has been removed, however, for example for a

cleaning procedure. The blocking teeth **144** now engage in the apertures **970** present in the side arms **960**, since the levers **143** are forced outwards by the pressure of the spring arms **142**. In this state, the protective cap **950** cannot be swung up in order to push it in. Thus, the absence of the mouthpiece **900** is made evident, and this precludes a situation where the patient puts the inhaler away without the mouthpiece **900** being fitted and cannot then use the inhaler in an emergency.

Figure 21C

In the desired *position B3*, the mouthpiece **900** is fitted. The connector plugs **911** of the mouthpiece **900** project into the receiving notches **109**. The bevels **931** of the connector plugs **911** here press the catches **145** of the levers **143** inwards, counter to the tensioning of the spring arms **142**, so that the blocking teeth **144** are drawn out of the apertures **970**. The protective cap **950** can thus be swung up again and closed.

Figures 22A and 22B

With correct positioning of the inhaler, i.e. when there is no over-critical inclination in the horizontal or in the axial axis of rotation, the blocking balls **130** position themselves centrally in the ball sockets **108** at the deepest points. In such a position, the protective cap **950** can be pulled out, since the appended carriage **500** is not blocked and can also be moved out.

If the inclination is over-critical, then the blocking balls **130** roll from the deepest points onto the lateral limits **116,120** and now lie higher up because of the oblique slopes in the ball sockets **108**. Outward travel of the carriage **500**

is now blocked. The blocking balls **130** now come into collision with the impact ridges **524** and the bulges **516**, so that ultimately the protective cap **950** cannot be pulled out. This safety measure guarantees that the inhaler is held in the correct position when it is opened, so that a correct filling of the dosing cavity **302** with medicament powder is ensured. The inhaler has to be opened in the prescribed position, but it can be used in any position once it has been opened, that is to say, in particular, also for patients who are lying down. A further control on its use is afforded by the fact that the protective cap **950** can only be swung downwards.

Figures 23A to 23G

This series of figures gives an impression of the successive construction of the inhaler, although this need not necessarily correspond with the sequence of assembly in mass manufacture.

The valve guide **850** is fitted into the rear of the lower part **100** of the housing and the valve shield **800** is fitted into the valve guide **850**. The mouthpiece **900** projects from the front, only one half of the mouthpiece **900** being shown for reasons of improved clarity (Figure 23A). The inhaler is equipped with the slide rail **200** placed near the mouthpiece **900** and with the carriage **500** bearing on the valve shield **800** (Figure 23B). The dosing slide **300** is now placed on the slide rail **200** (Figure 23C). The shutter **400** is added for further completion (Figure 23D). The protective cap **950** with the lateral side arms **960**, which are attached to the carriage **500**, is now fitted (Figure 23E). The completely fitted funnel arrangement **600**, which is directed towards the protective cap **950**, and the counter **700** are shown here in two

views (23F, 23G). Finally, the upper part **150** of the housing would have to be fitted.

Further constructional variations can be made to the inhaler which has been described. The following variations are expressly mentioned here:

- Instead of the dimples **972** for arresting the protective cap **950** in the pushed-in state - *situation A1* - an outwardly directed cam could in each case be provided near the entrance to the cap **952** on the upper side of the side arms **960**, which cams engage in slots in the front side **160** of the upper part **150** of the housing in the closed state. In order to detach the protective cap **950** from the mouthpiece **900**, the protective cap is to be pressed-in in the area of the lateral grip contours **951**, as a result of which the cams come out.

- In the mouthpiece **900**, near the channel outlet **922**, it is possible to provide in the enlarged channel section **928** a three-dimensional surface-profiled wall section with a transverse fluting in order to promote the powder deagglomeration and the deposition of coarser particles ineffective for inhalation.

- To hold the two halves of the mouthpiece **900** together, complementary connecting elements could be arranged in each case on the inner cut edges of the two halves - for example, a combination of bores and cams - in order for both halves to be joined together again after possible cleaning and drying.

- To embed the funnel arrangement in the inhaler, it might be possible to use a collar made of elastic material which is pushed onto the funnel holder **601**.

- The pharmacological dry powder stored in the funnel **690** can be in loose form on the one hand. However, pre-dosed units for dispensing are also included, for example as extruded pellet lane or in pearl chain form. Individually dosed units for dispensing could be arranged in blisters or on tape rolls. It will be appreciated that the medicament reservoir and a device for dividing off the individual doses are to be designed in accordance with each other.

- Irrespective of the greater outlay in terms of manufacturing technology, the above-described two-part housing, consisting of the lower part **100** of the housing and the upper part **150** of the housing, could also be made in one piece.

- The atomizer path **924** in the mouthpiece **900** is designed as a straight or winding channel in which at least one baffle **925** is arranged, and the latter can be an inwardly projecting lamella, a wall, a flow body or a screen.

- Instead of the mechanical counter **700**, it is also possible to use a chip with which all relevant data are recorded, such as number of inhalations performed, time of intake, and flow parameters.

- The flow control realized at present by means of the overspring rib **157** and the spring arms **822** could also be obtained by means of an alterable resistance within the valve guide **850**.

- To regulate the flow rate, it is advantageous to provide an insert for receiving an optional nozzle within the mouth tube **920**, namely at the start of the atomizer path **924** or mounted upstream of the mouth tube.

- For specific changing of the flow resistance in the inhaler during an inhalation, which resistance is obtained by the air gap between the fixed valve guide **850** and the

moving capsule **810** of the valve shield **800**, it is possible to configure this air gap, effective at the respective position of the valve shield **800**, incrementally by means of physical irregularities on the surface of the capsule **810** and/or in the inside of the valve guide **850**. For this purpose, consideration may be given, for example, to widening or narrowing physical dimensions on the capsule **810** of the valve shield **800** and in the valve guide **850** or grooves whose cross-section changes along their length.

- In the inhaler which has been described, but also in inhalers in general, there is the possibility of recording the inhalations and their flow parameters by means of sensor technology. To measure the parameters, use is made of membrane/bending beam technology or a piezoresistive element in combination with a diaphragm or in combination with the Venturi measurement principle. With IPC logic and sensor technology, open-loop control becomes closed-loop control. This closed-loop control makes it possible to govern an adjustable nozzle via an electronic movement element, which nozzle finally regulates the flow in the inhaler constantly by a resistance change.

- For current supply, a dynamo is provided in the inside of the inhaler and generates an electric current when the protective cap **950** is opened or when air flows through the inhaler during the inhalation, this electric current being stored and being used to supply the electronic components.

- The electronic components, as a plug-in, re-usable control module, can be removed from the inhaler so that a battery operation is possible. The inhalation data are collected by means of an integrated memory chip and made available to the doctor or pharmacist. Exact monitoring of the dose administration is thus possible. The plug-in modules can be recharged on base units for further use and/or can be

programmed so that only the contaminated part of the inhaler is to be discarded.

- To better monitor the inhalation procedure, a mechanically and/or electronically generated acoustic and/or optical signal is emitted on completion of a successful or unsuccessful inhalation.

- It is also possible to arrange the two complementary grate sections **515,621** on the one hand on the carriage **500** and on the other hand on the lower part **100** of the housing or on the upper part **150** of the housing. So that vibrations occur only when the protective cap **950** is being pulled out - but not when it is being pushed back - one of the two grate sections **515,621** can be taken out of operation on each replacement of the protective cap **950**, e.g. on a component which is also movable.

- The desiccant powder at present accommodated in the funnel lid **680** inside the chamber **681** could also be positioned inside the funnel holder **601**.

- The outer contours of the inhaler and the internal weight distribution mean that when it is laid on an essentially horizontal and dimensionally stable support, the inhaler always orients itself with the outlet **608** of the funnel holder **601** pointing downwards.

20152-1242D

CLAIMS:

1. A mouthpiece for an inhaler, comprising:

a channel inlet;

a mouth tube having an end face with an upper portion and a channel outlet located in said upper portion of said end face; and

an atomizer path extending within said mouth tube from said channel inlet to said channel outlet, said atomizer path including a first channel section and a second channel section, said first channel section having at least one baffle and being in communication with said channel inlet and located at a first level, said second channel section being in communication with said first channel section and said channel outlet,

said second channel section including a first portion located at said first level, said first portion communicating with said first channel section and having a larger volume than said first channel section, and a second portion located at a second level which is higher than said first level, said second portion being in communication with said channel outlet of said mouth tube,

and said channel outlet including a horizontally oriented slit located in said upper portion of said end face of said mouth tube.

2. A mouthpiece according to claim 1, wherein said first channel section of said atomizer path is formed by walls and said walls form said at least one baffle.

3. A mouthpiece according to claim 1 or claim 2, wherein said first channel section includes a plurality of

baffles which protrude into said atomizer path thereby forming a plurality of curves within said atomizer path.

4. A mouthpiece according to any one of claims 1 to 3, further comprising a ramp which is positioned at the channel inlet.

5. A mouthpiece according to any one of claims 1 to 4, wherein said mouthpiece is a multi-part component which includes at least two parts.

6. A mouthpiece according to claim 5, wherein said at least two parts of said mouthpiece are connected to one another by an integral hinge.

7. A mouthpiece according to claim 6, wherein said at least two parts of said mouthpiece include two symmetrical halves having complementary connecting elements, and wherein said integral hinge is located on an outer end face of said mouthpiece.

8. A mouthpiece according to any one of claims 1 to 7, wherein said mouth tube of said mouthpiece has an elliptical cross-section having a vertical height and a horizontal width which is greater than said vertical height, and a longitudinal axis which is transverse to said elliptical cross-section.

9. A mouthpiece according to any one of claims 1 to 8, wherein said mouthpiece is adapted for use with an inhaler for administration of pharmacological dry powder.

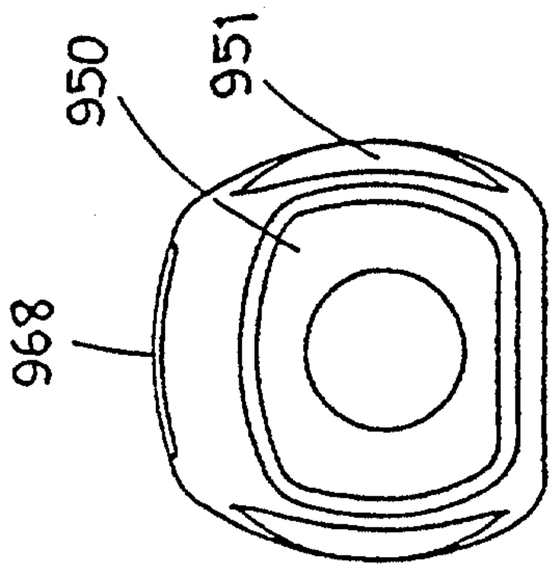


Fig. 1A

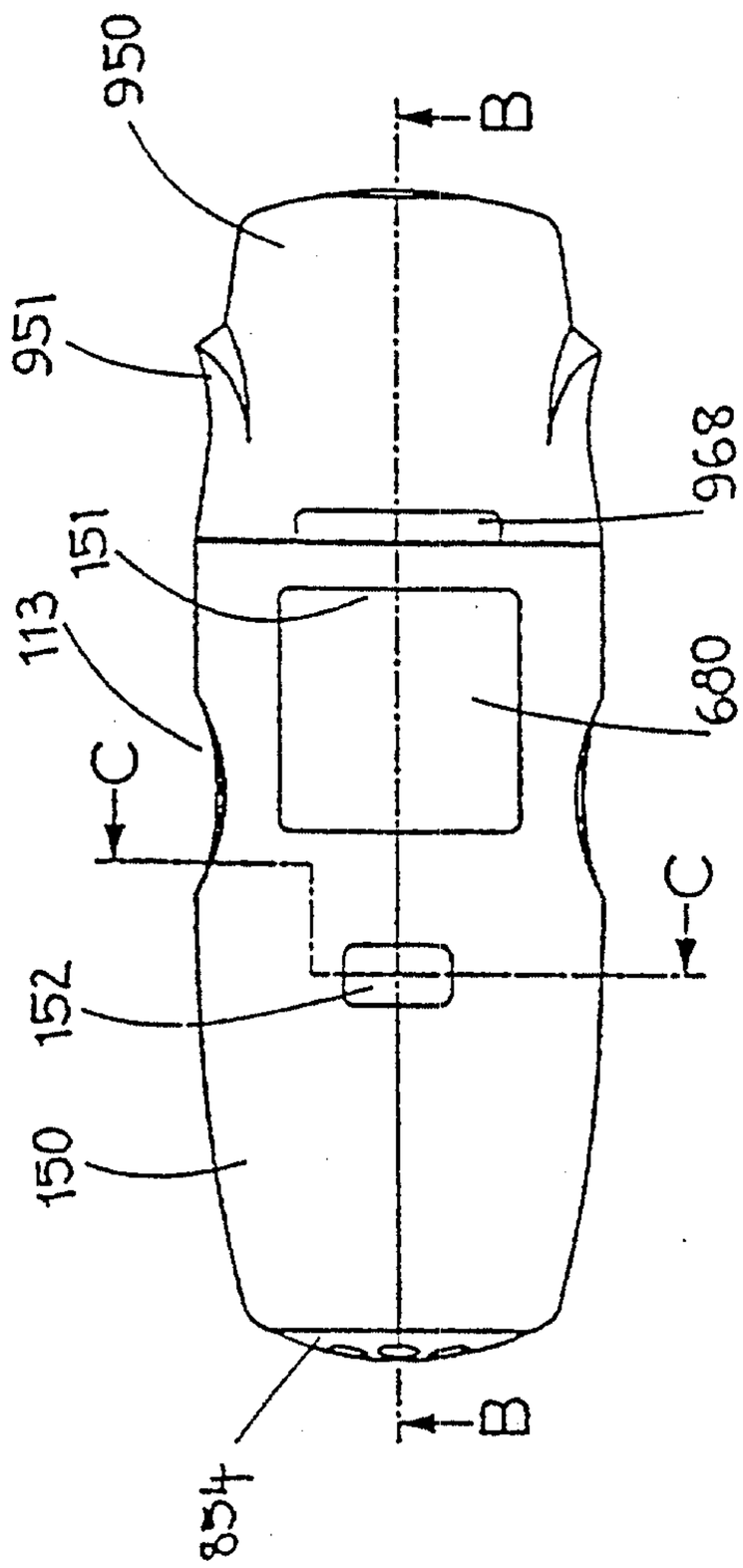


Fig. 1C

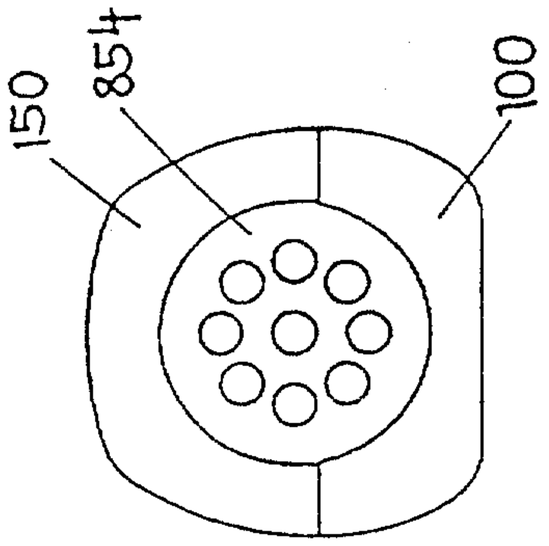


Fig. 1B

Fig. 1D

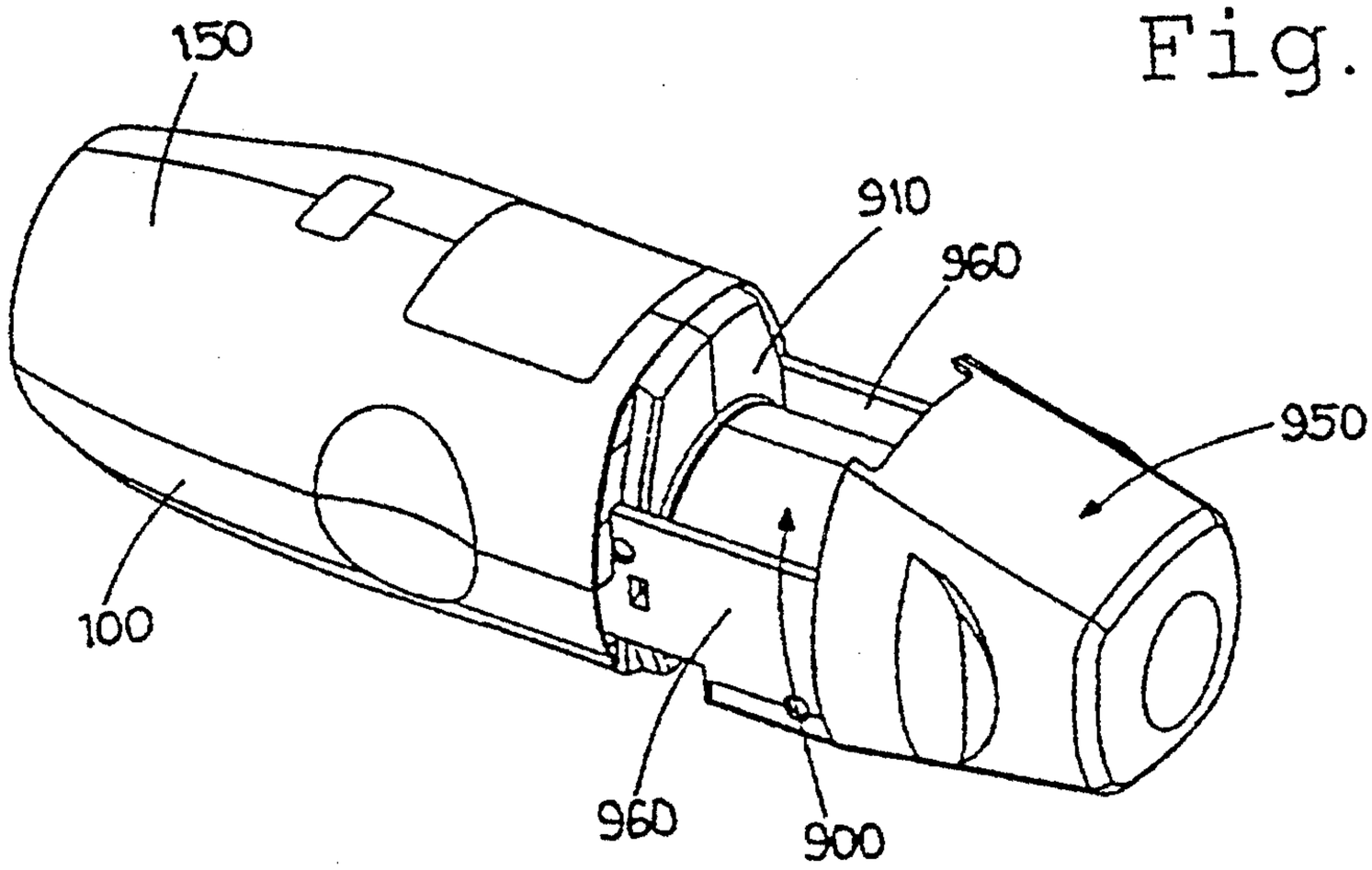


Fig. 1E

Fig. 1F

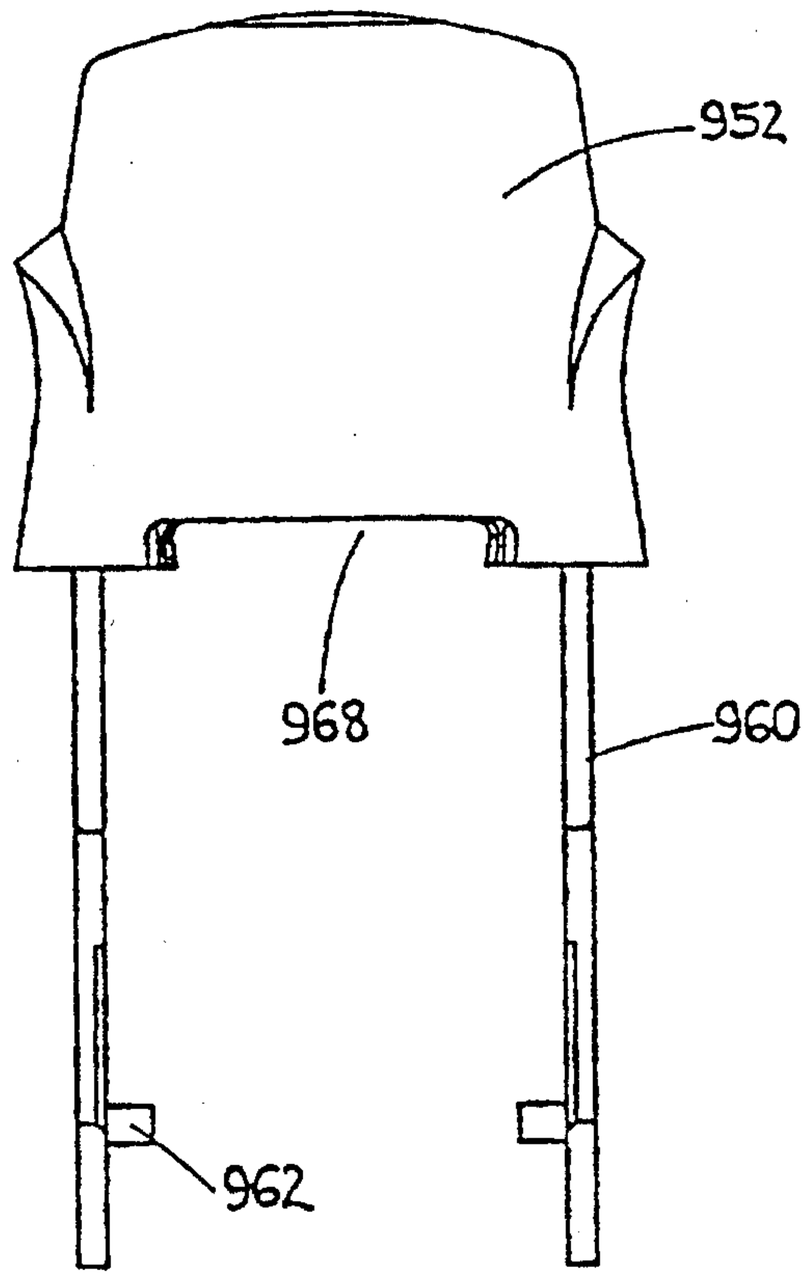


Fig. 2B

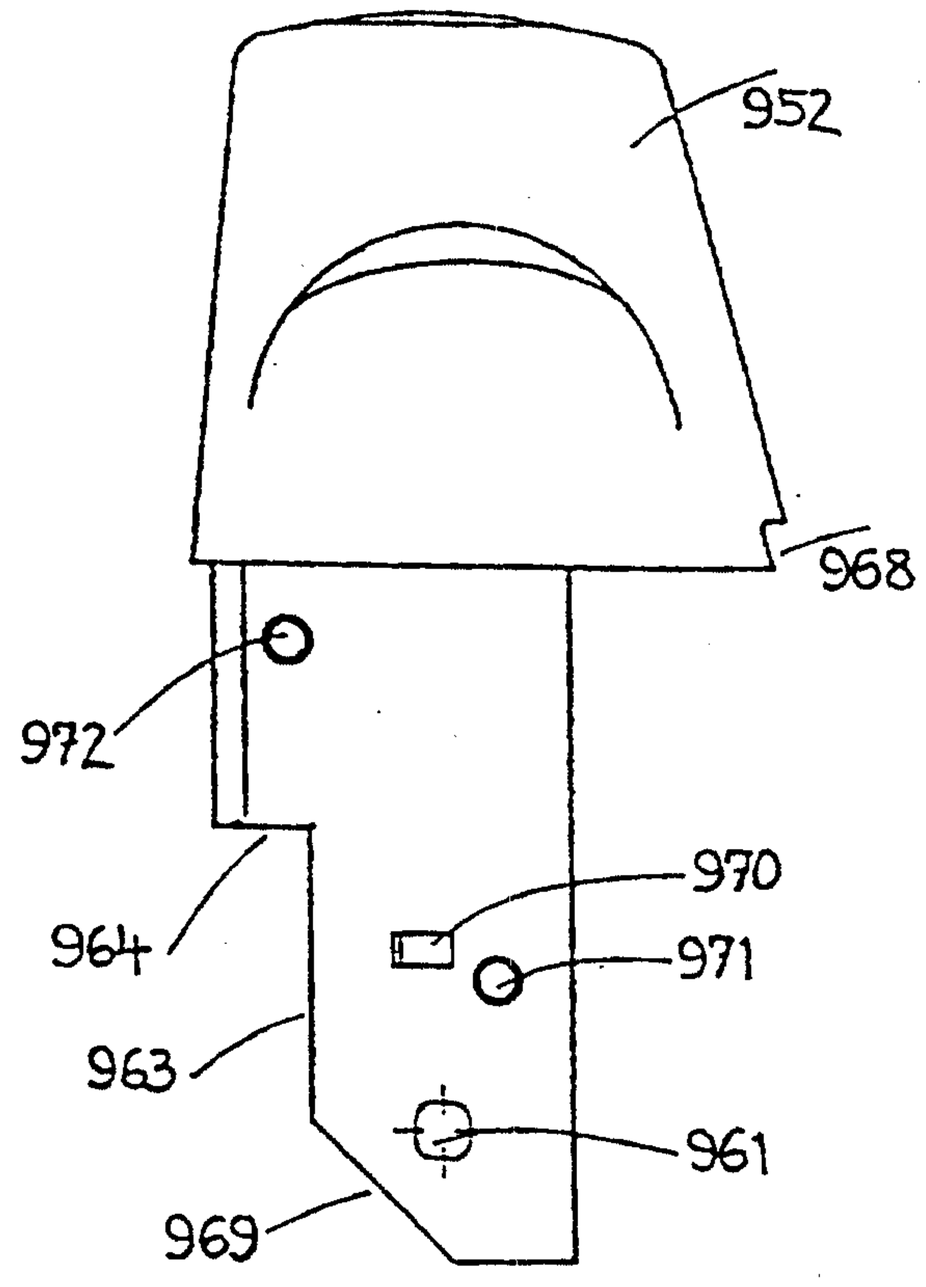


Fig. 2C

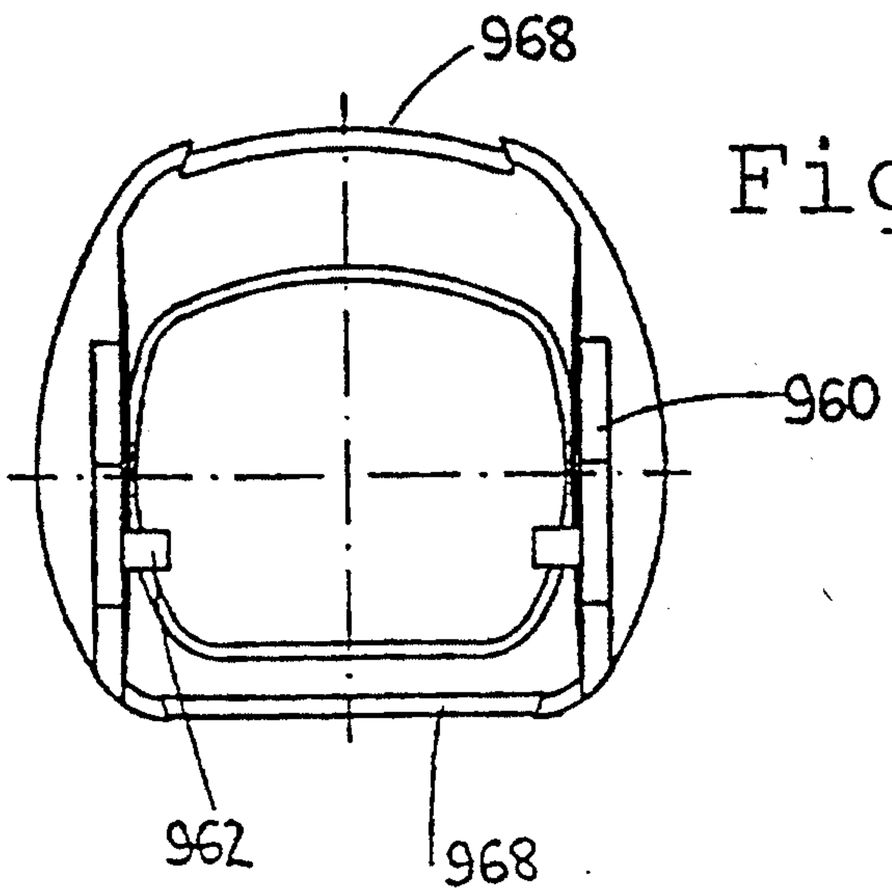


Fig. 2D

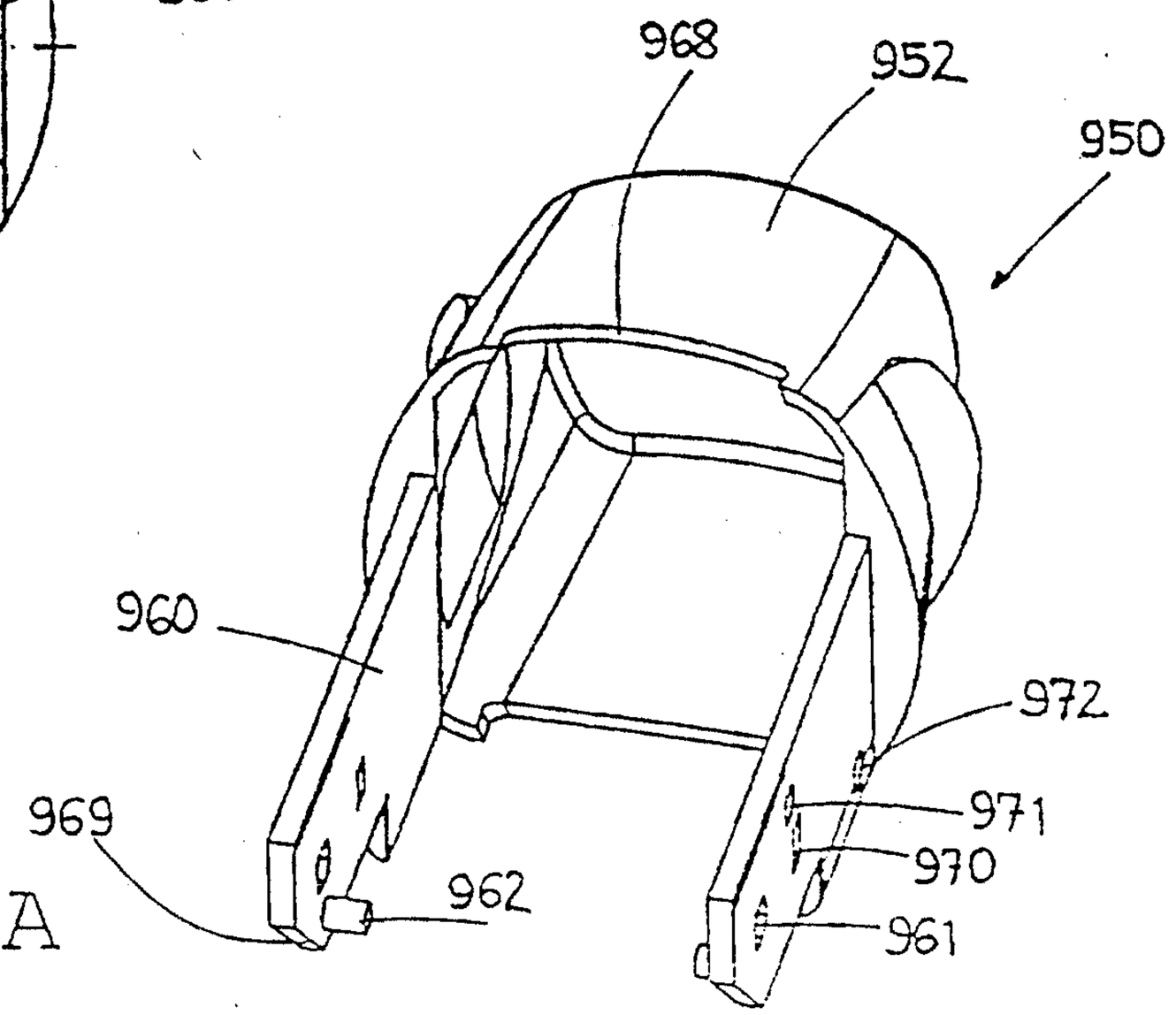


Fig. 2A

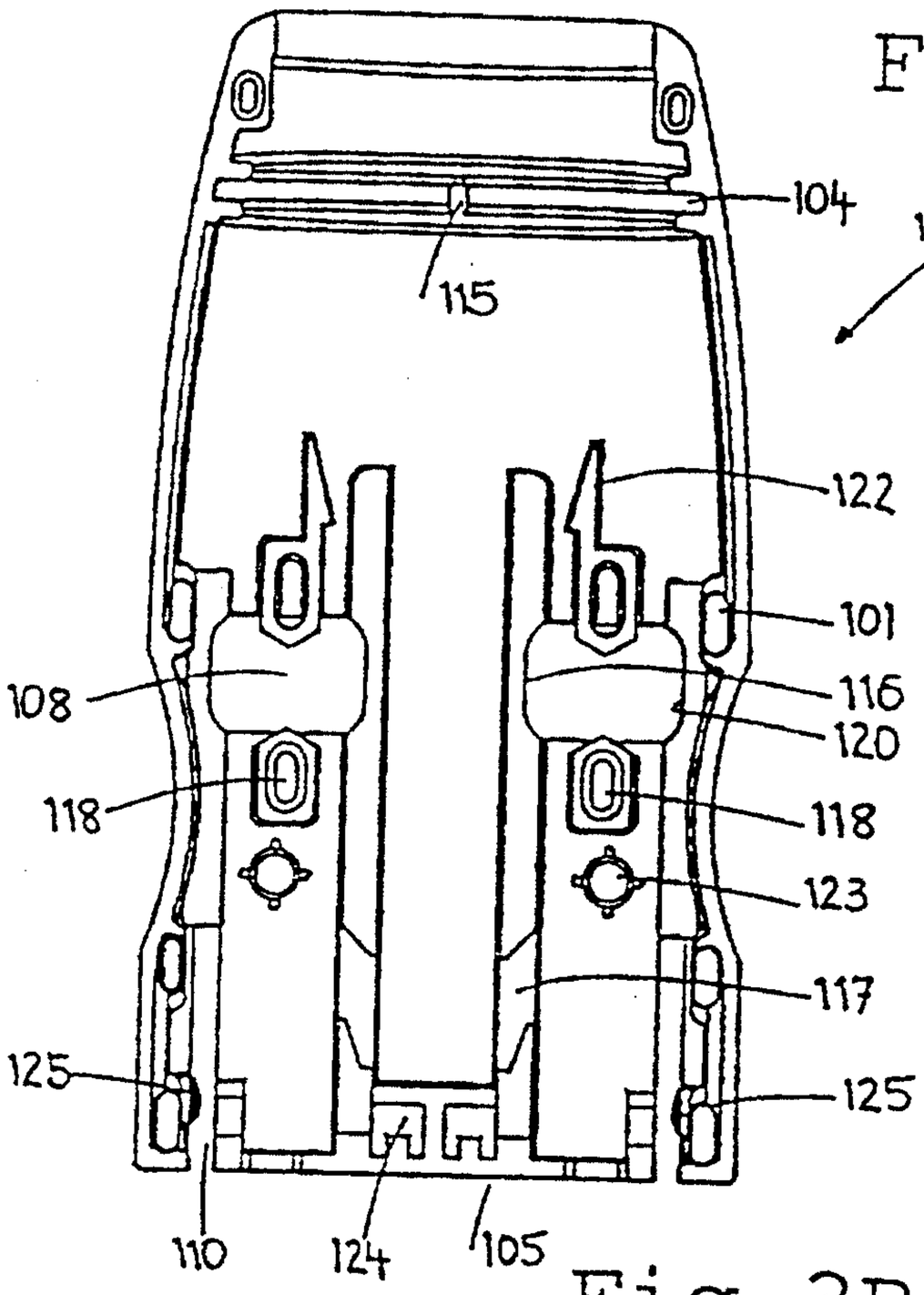


Fig. 3C

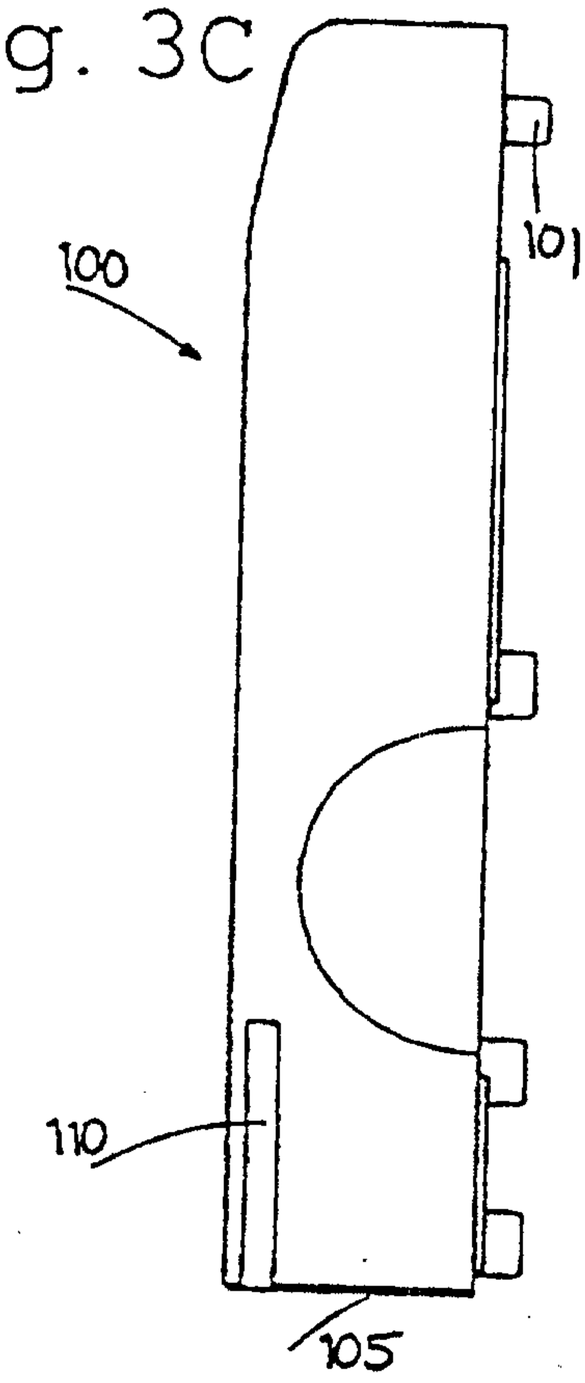


Fig. 3B

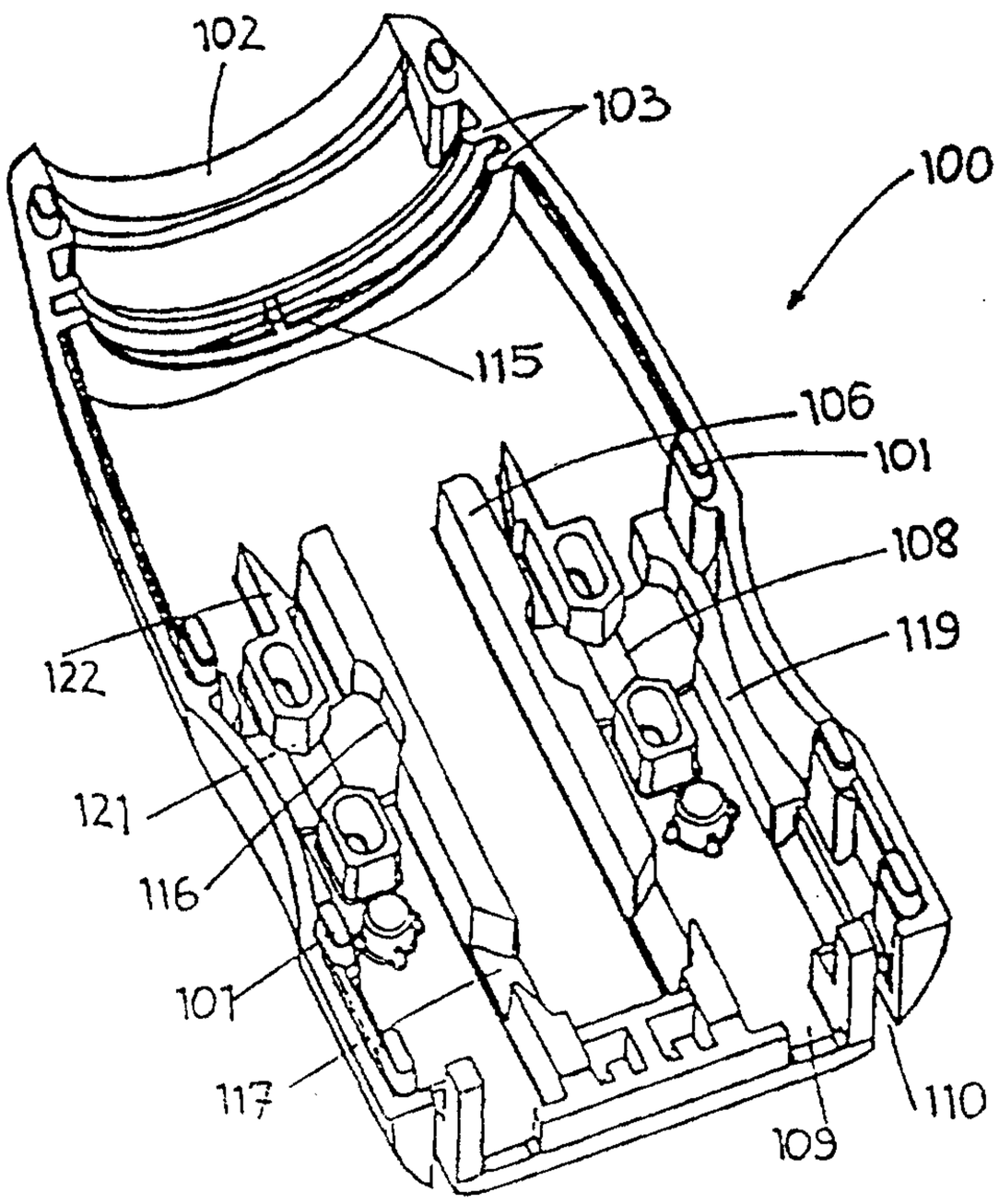


Fig. 3A

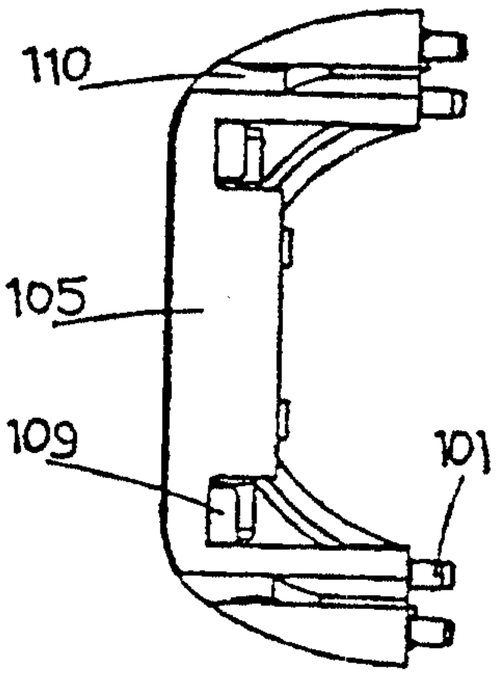


Fig. 3D

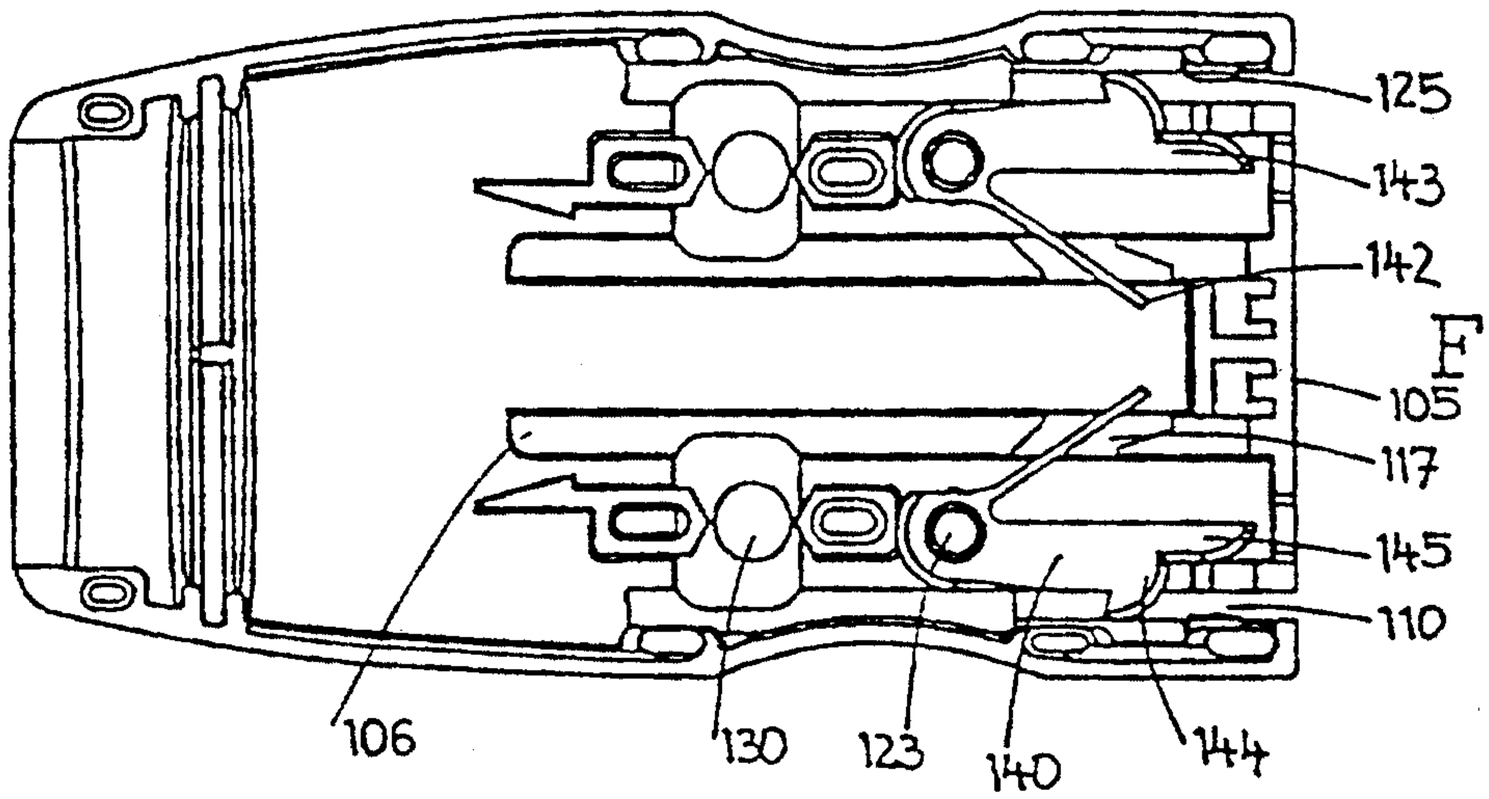


Fig. 3F

Fig. 3E

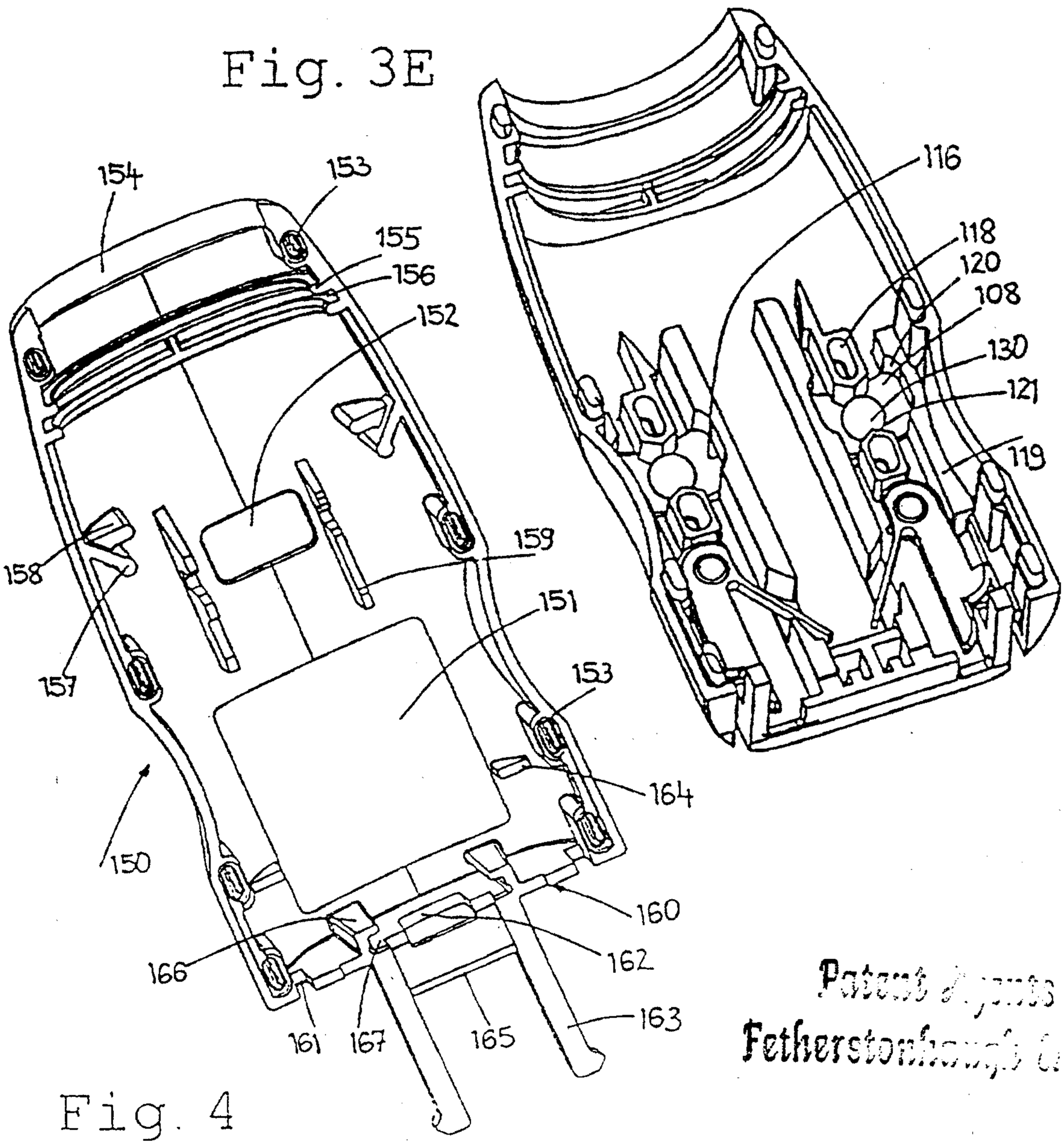
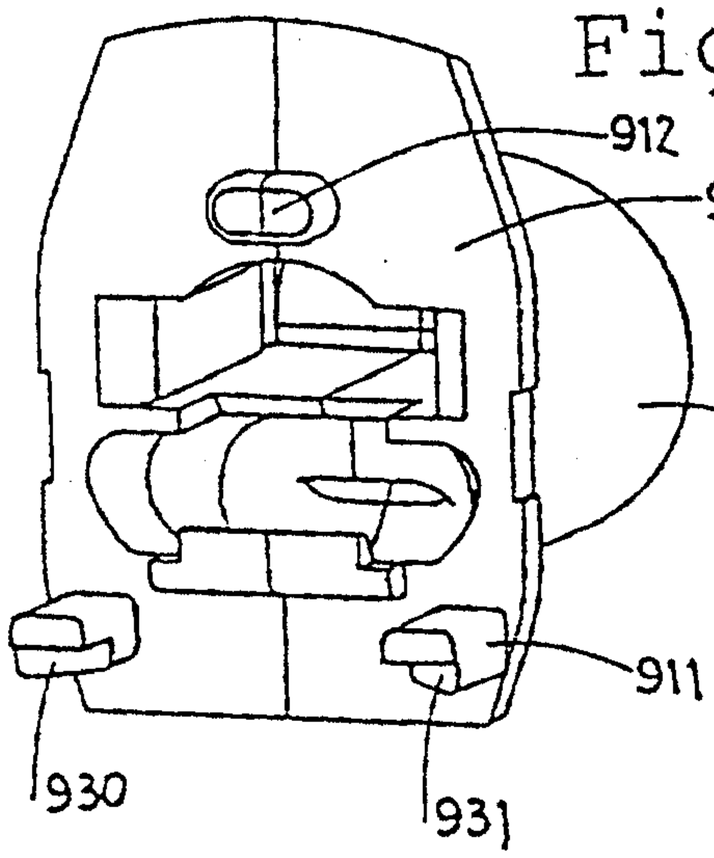


Fig. 4

Patent drawings
Fetherstonhaugh & Co.

Fig. 5A



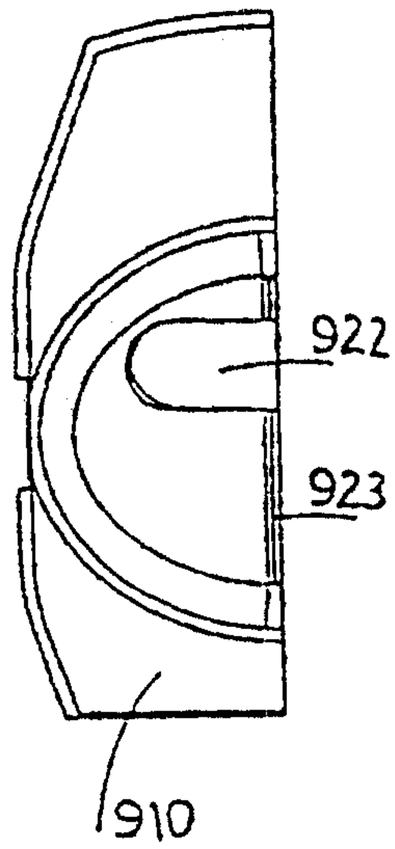


Fig. 5C

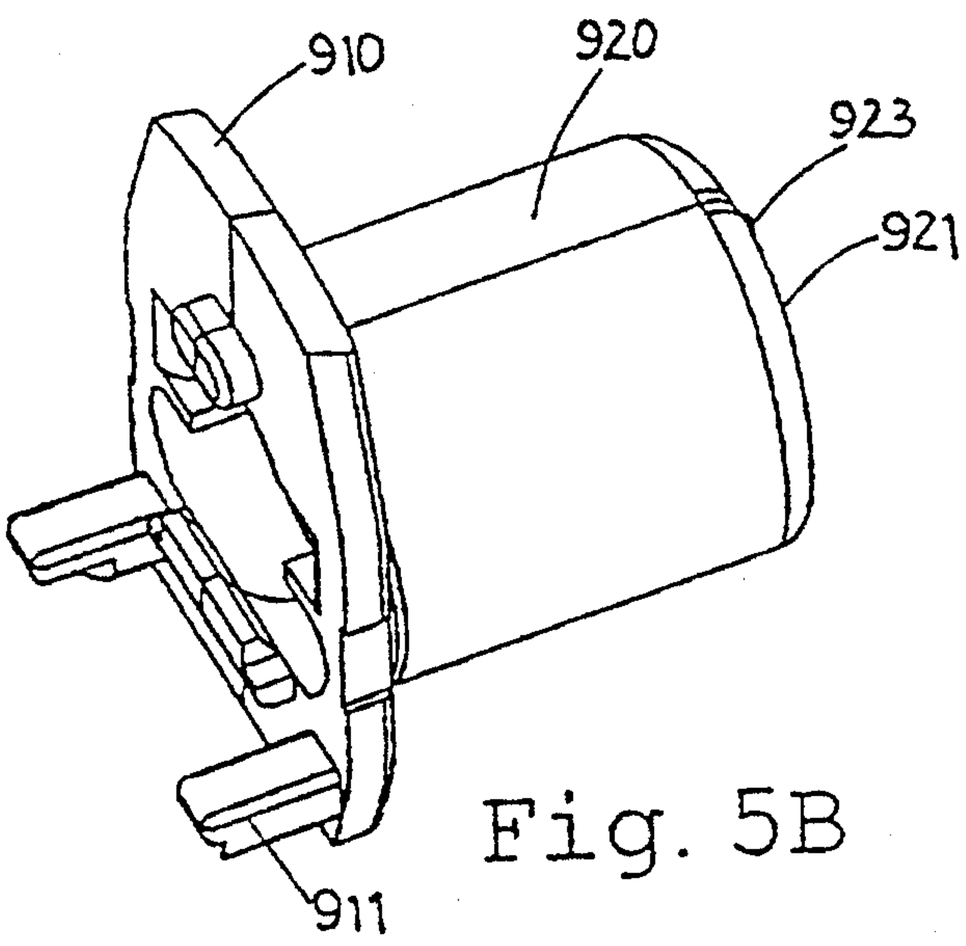


Fig. 5B

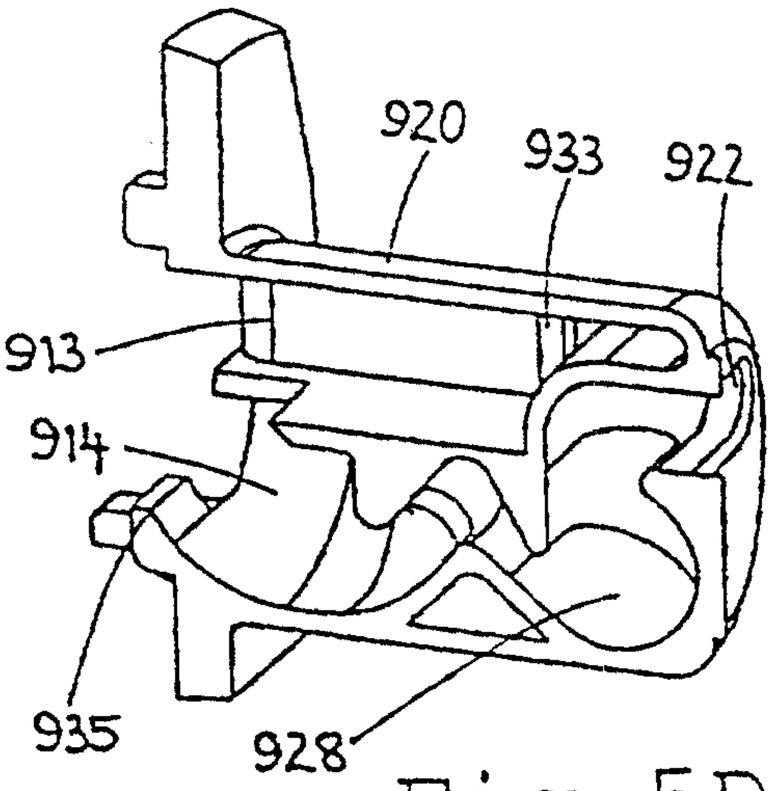


Fig. 5D

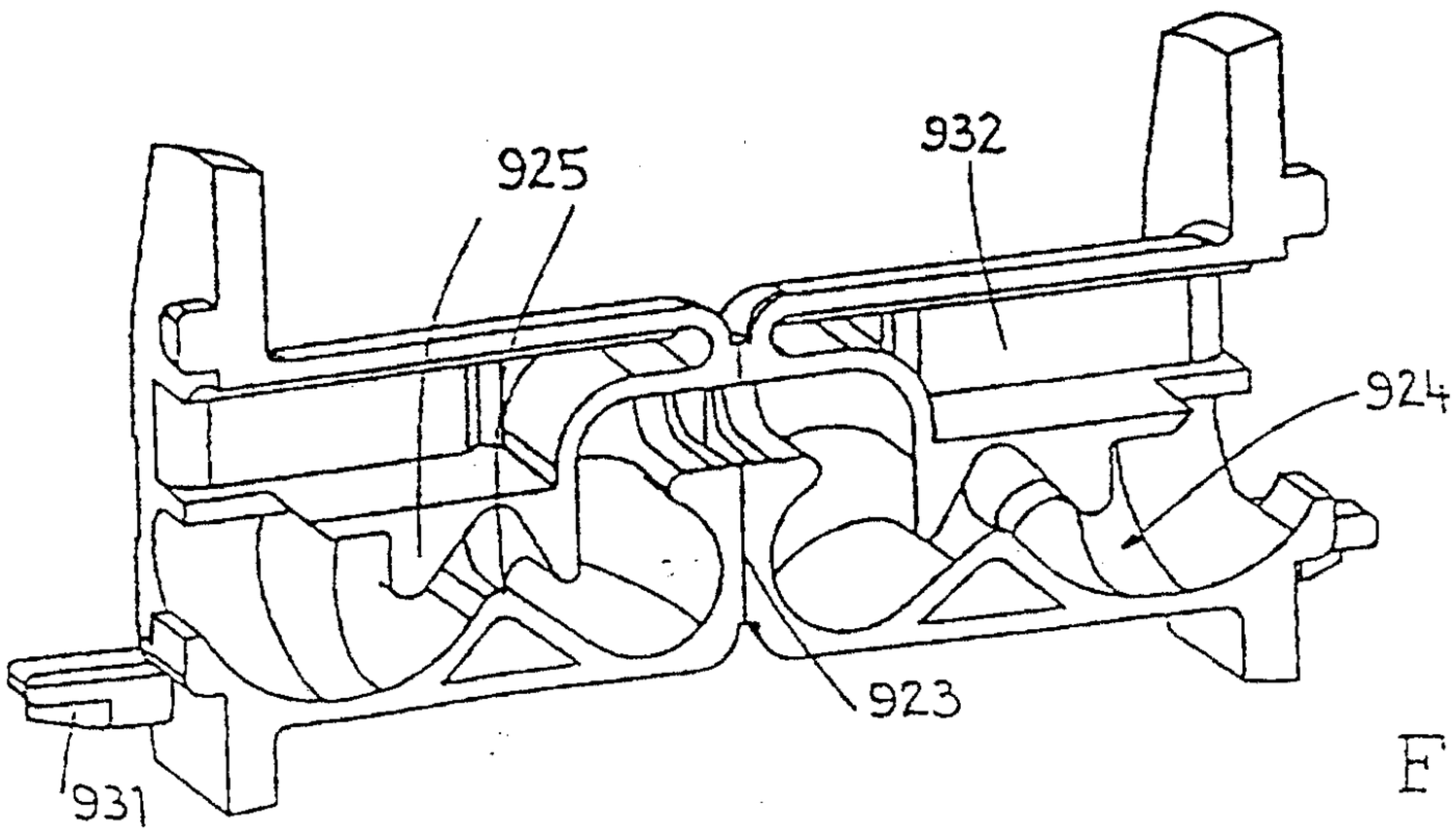


Fig. 5E

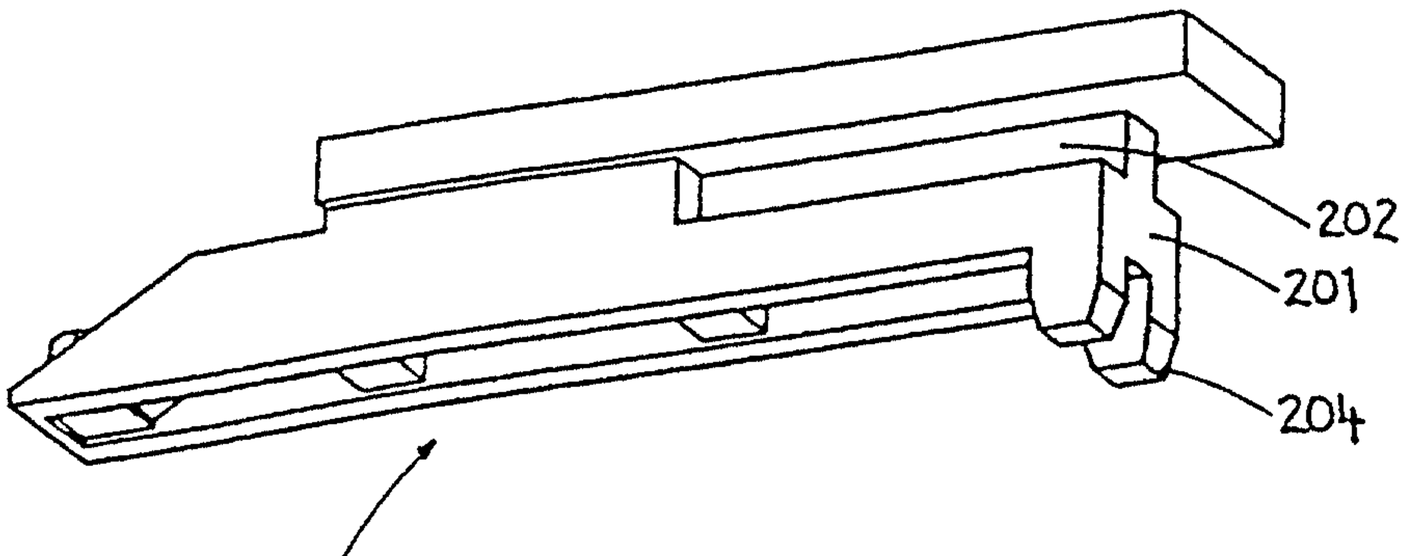


Fig. 6A

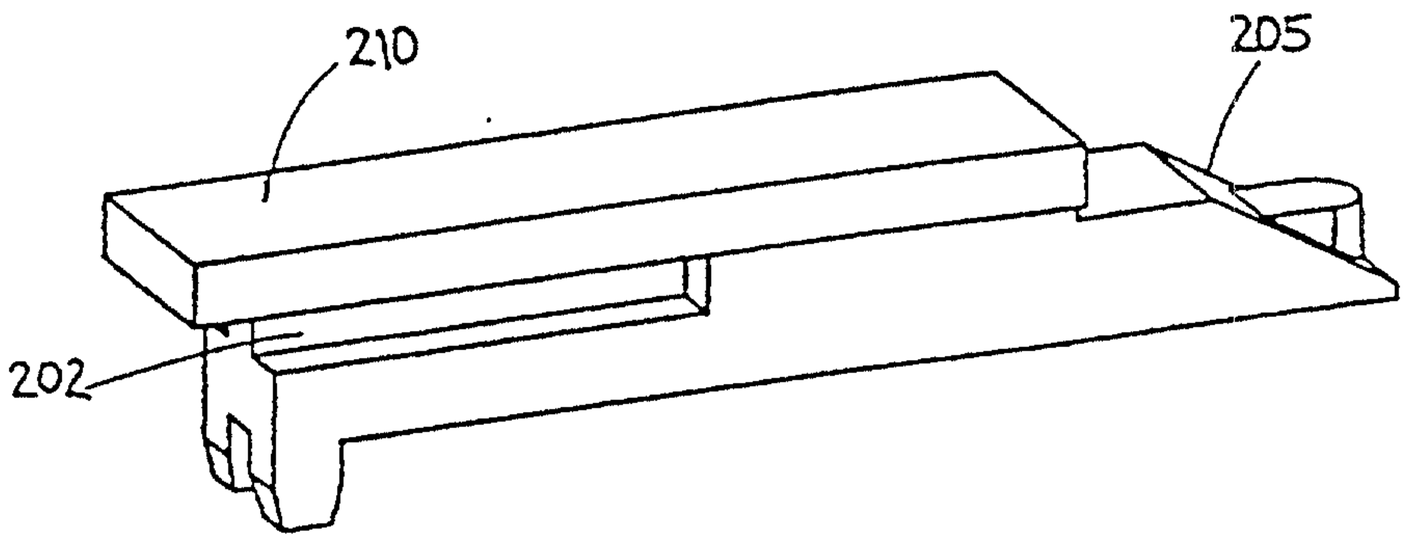


Fig. 6B

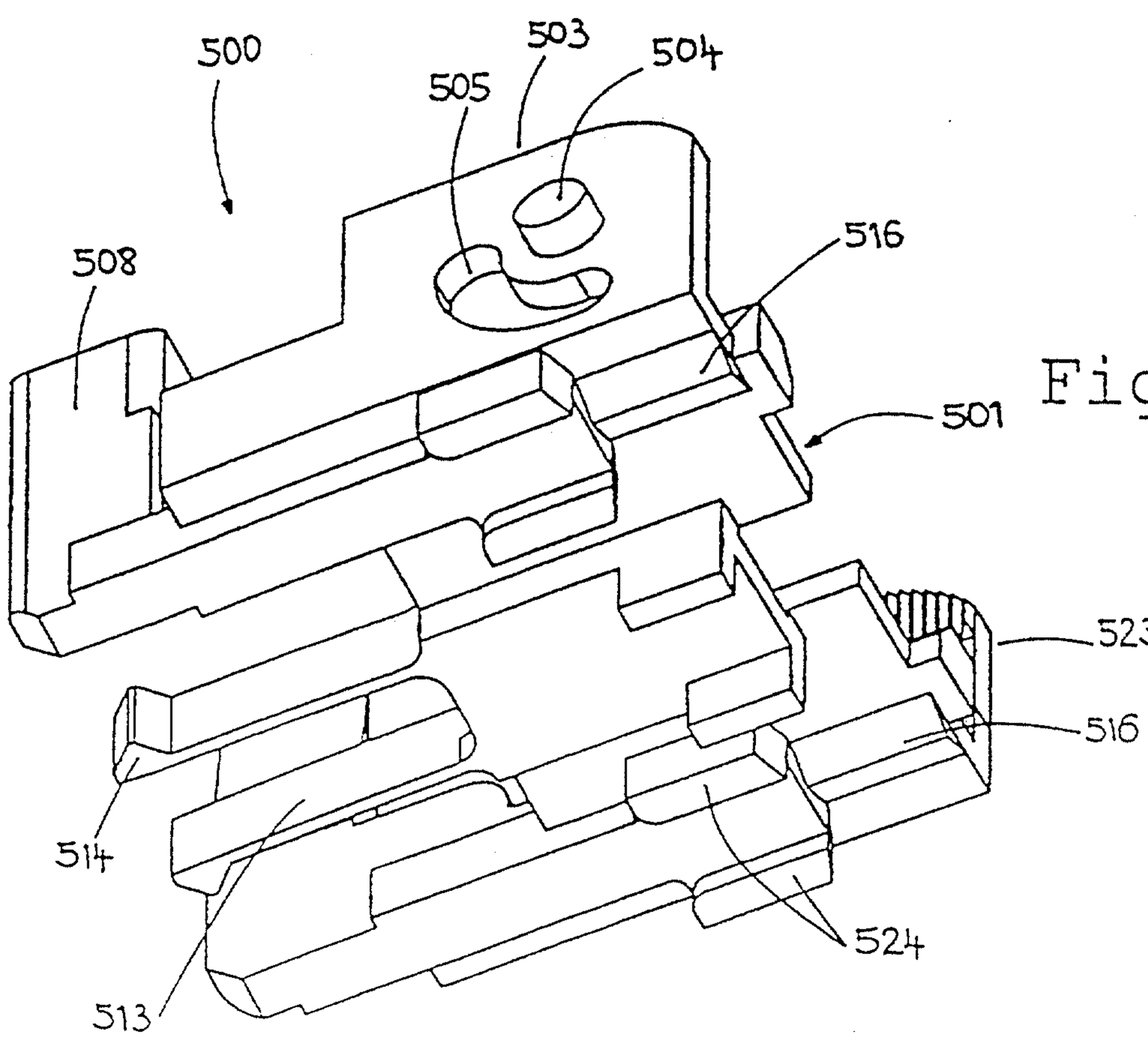


Fig. 7A

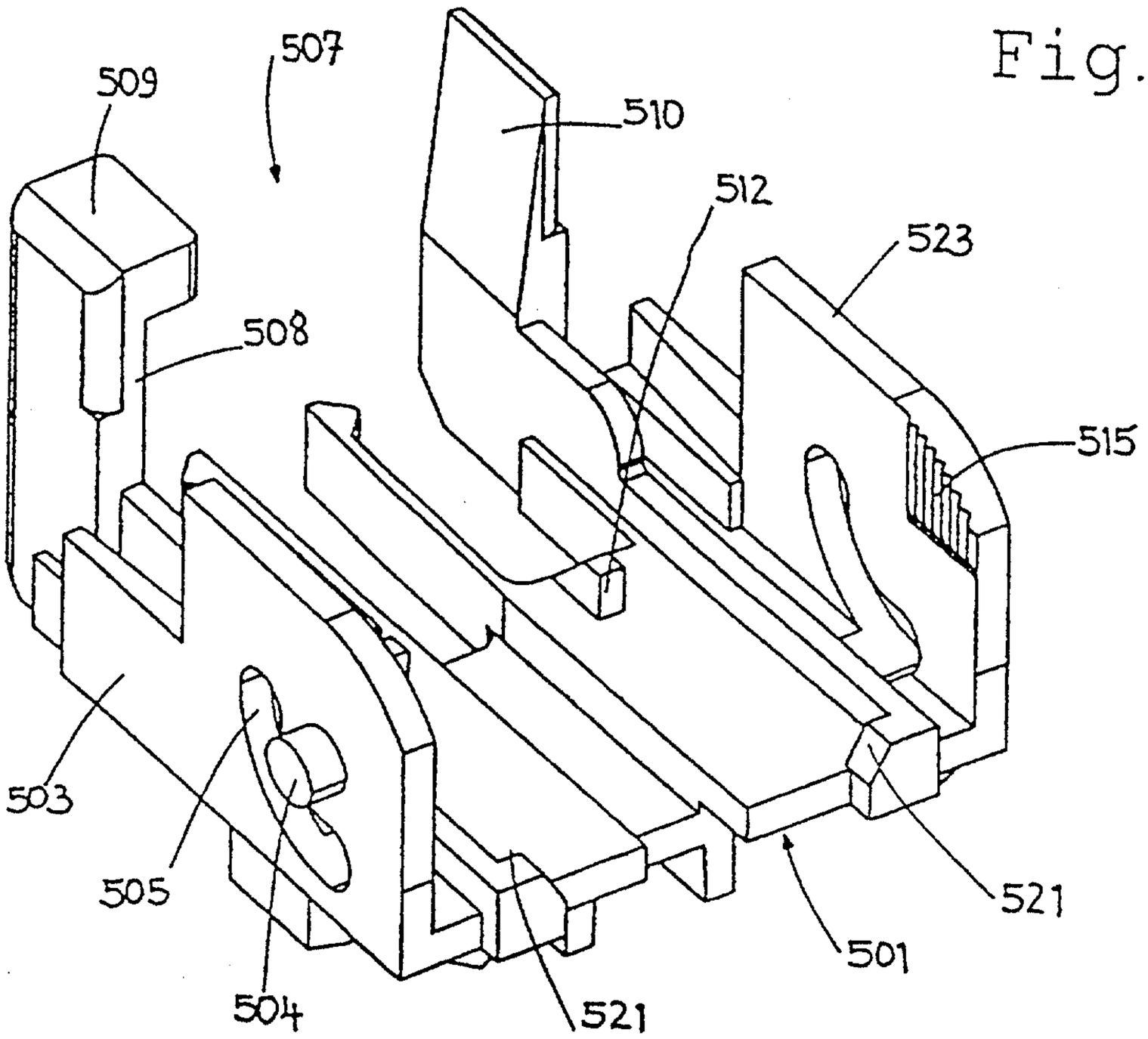

507
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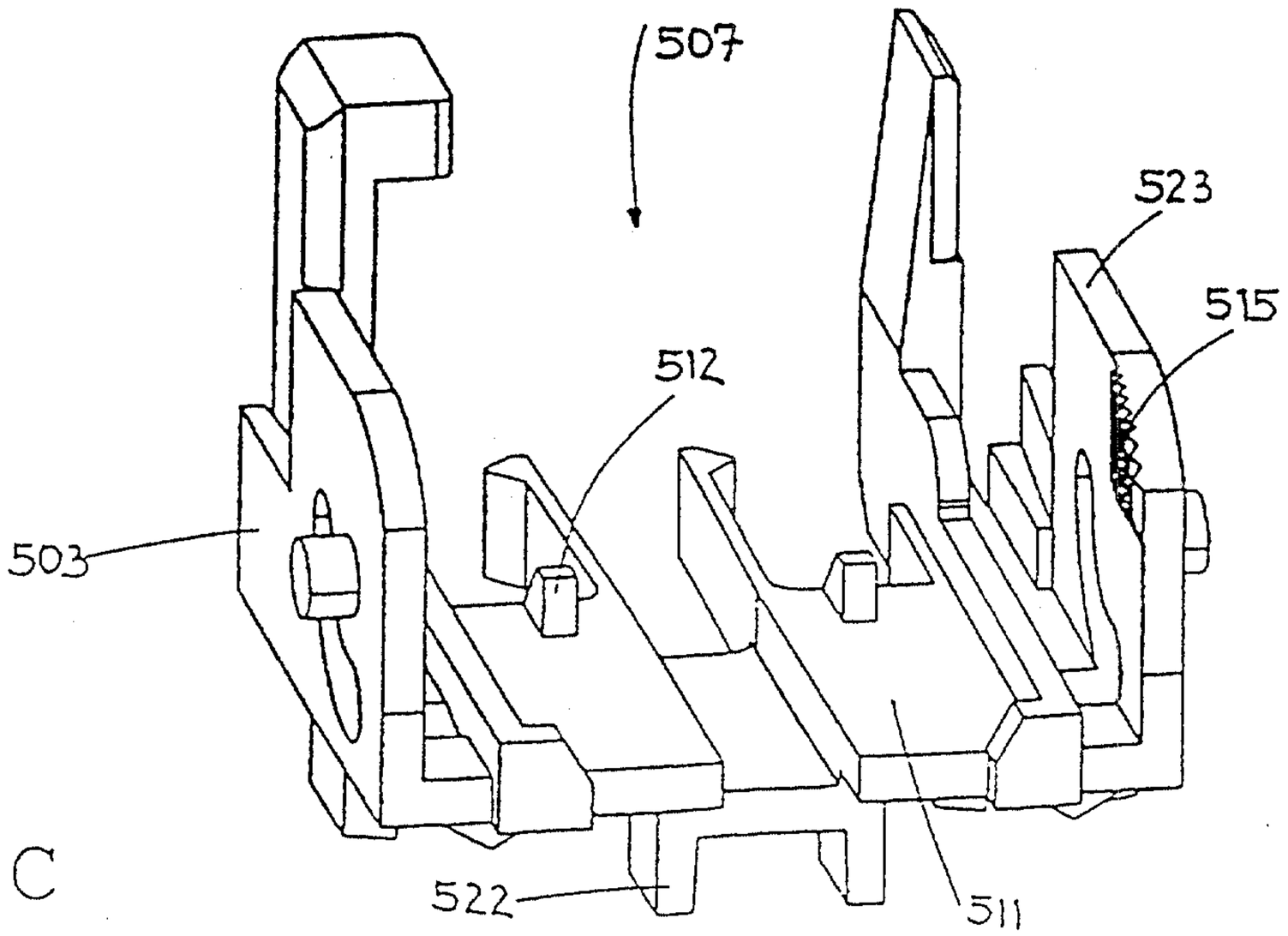
Fig. 7B


507
523
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503
522
511

Fig. 7C

Fig. 7D

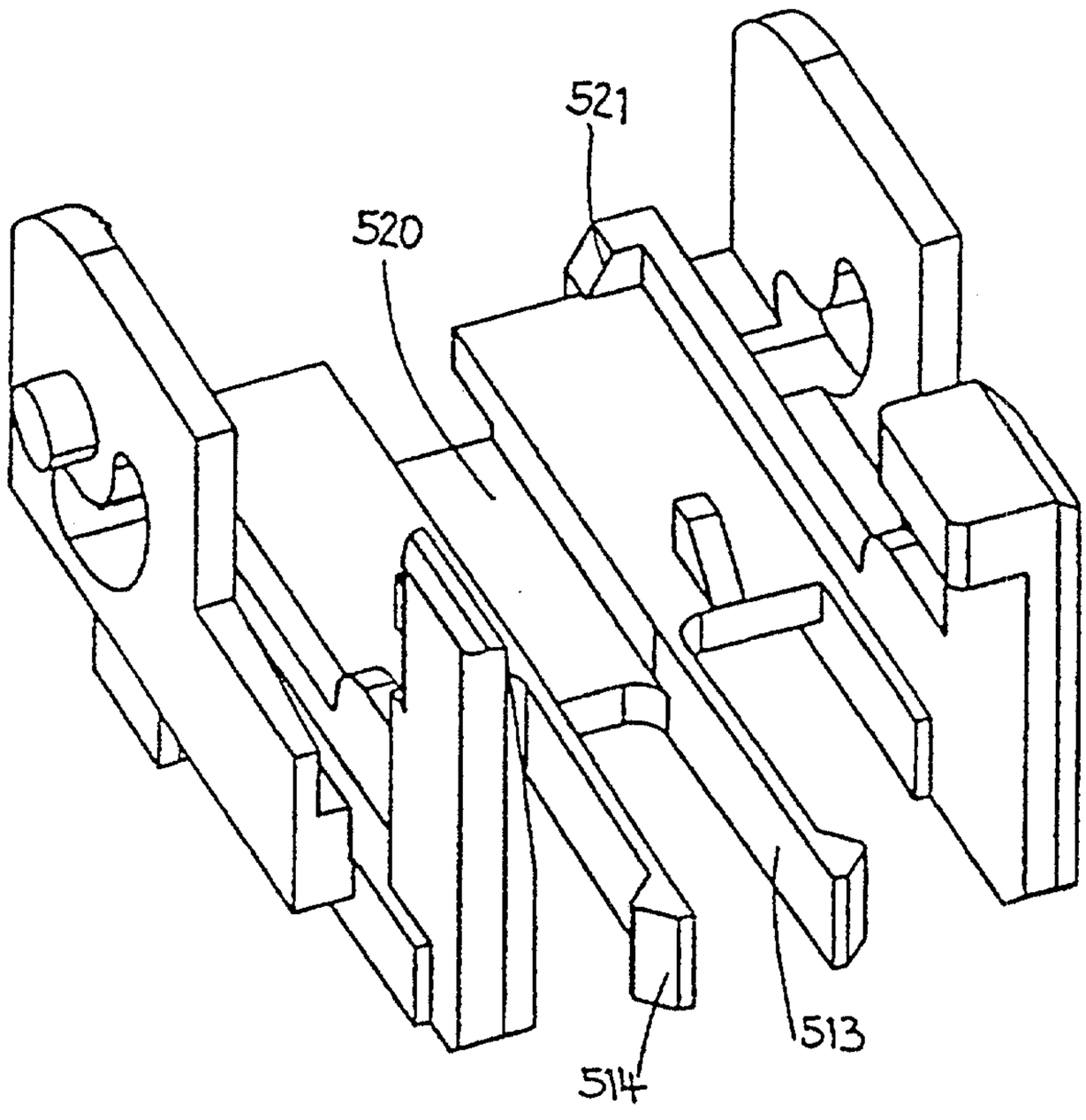
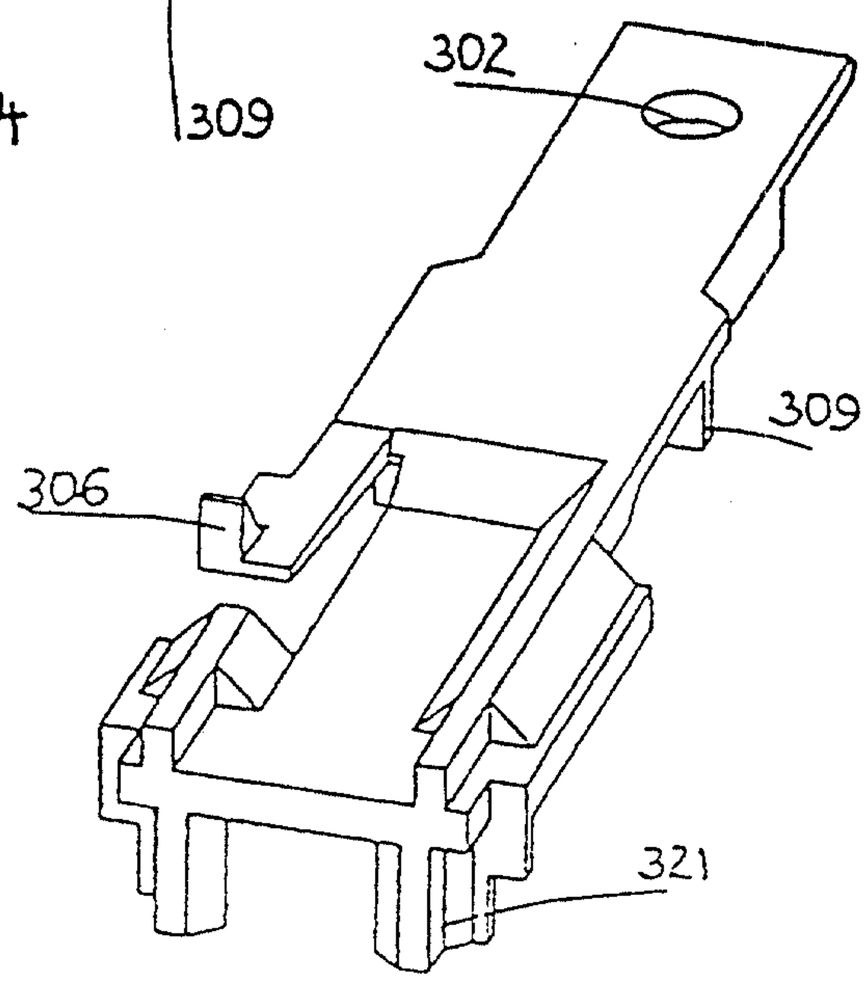


Fig. 8A

Fig. 8B



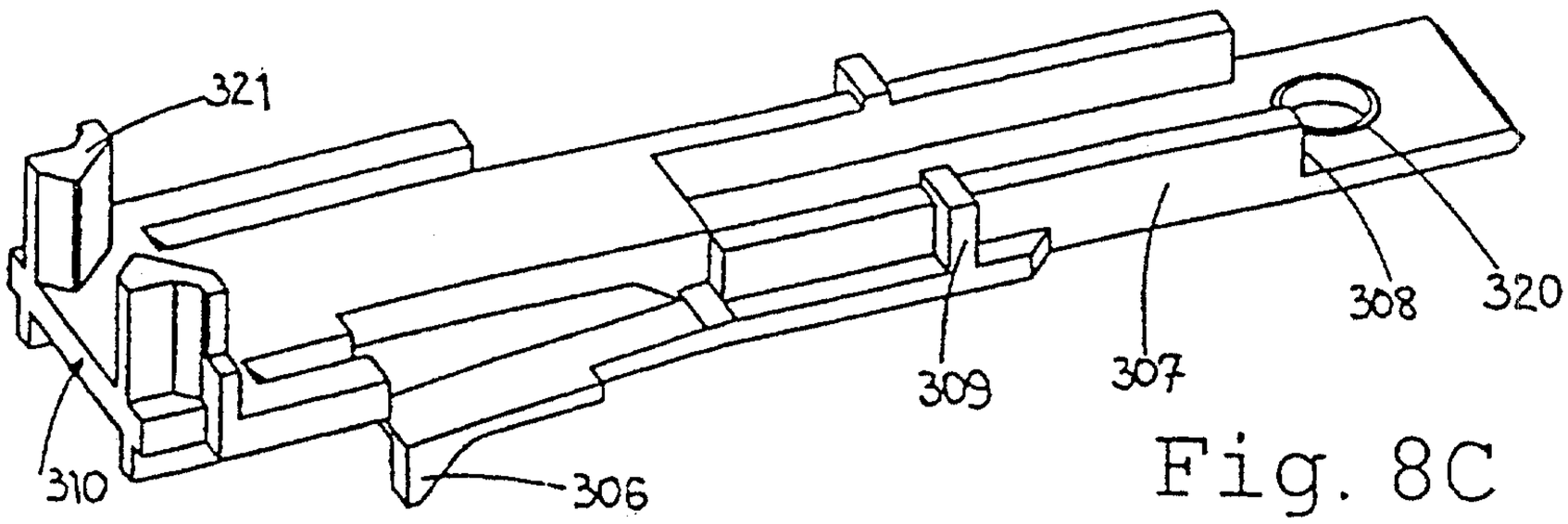


Fig. 8C

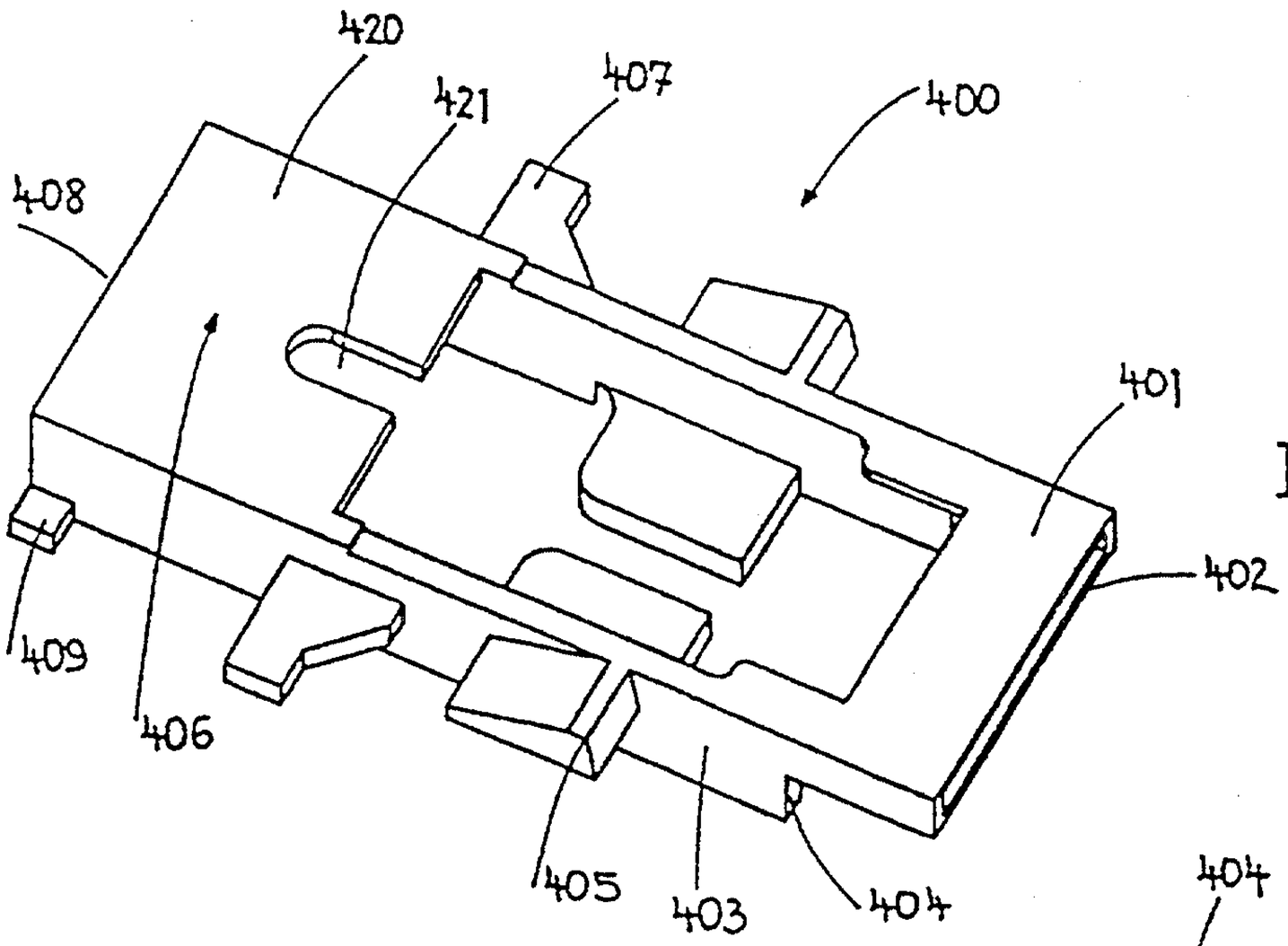


Fig. 9A

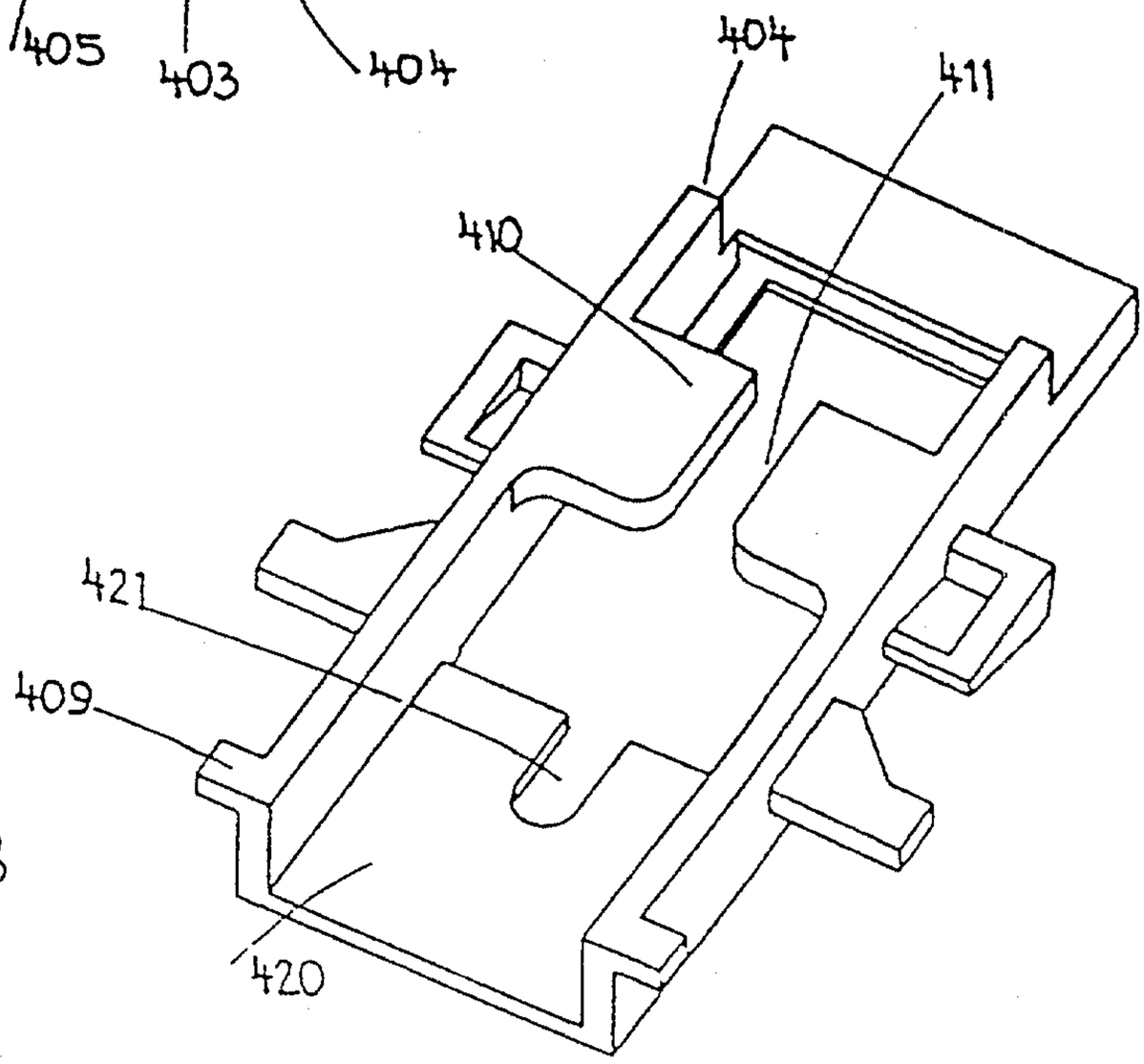


Fig. 9B

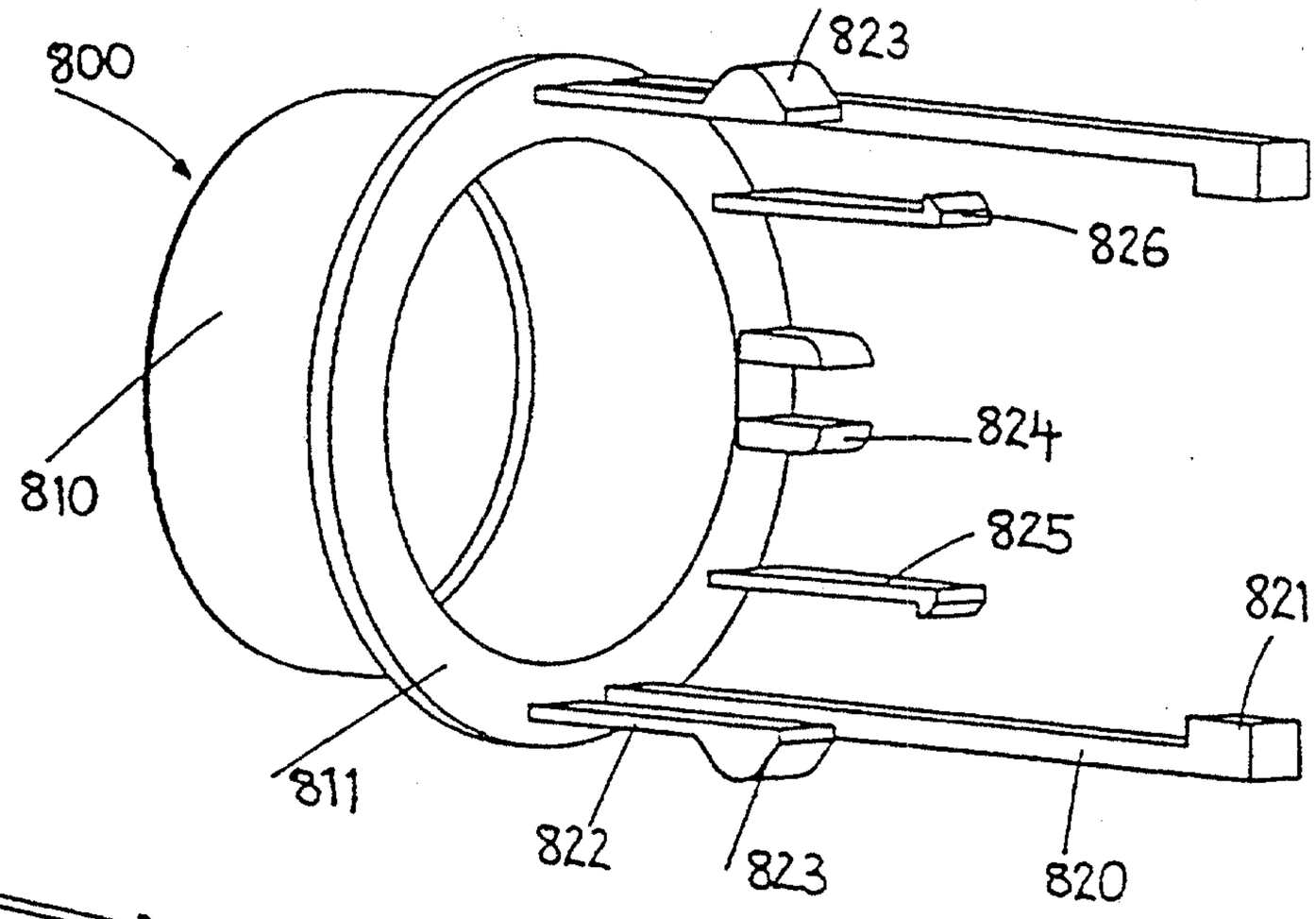


Fig. 10A

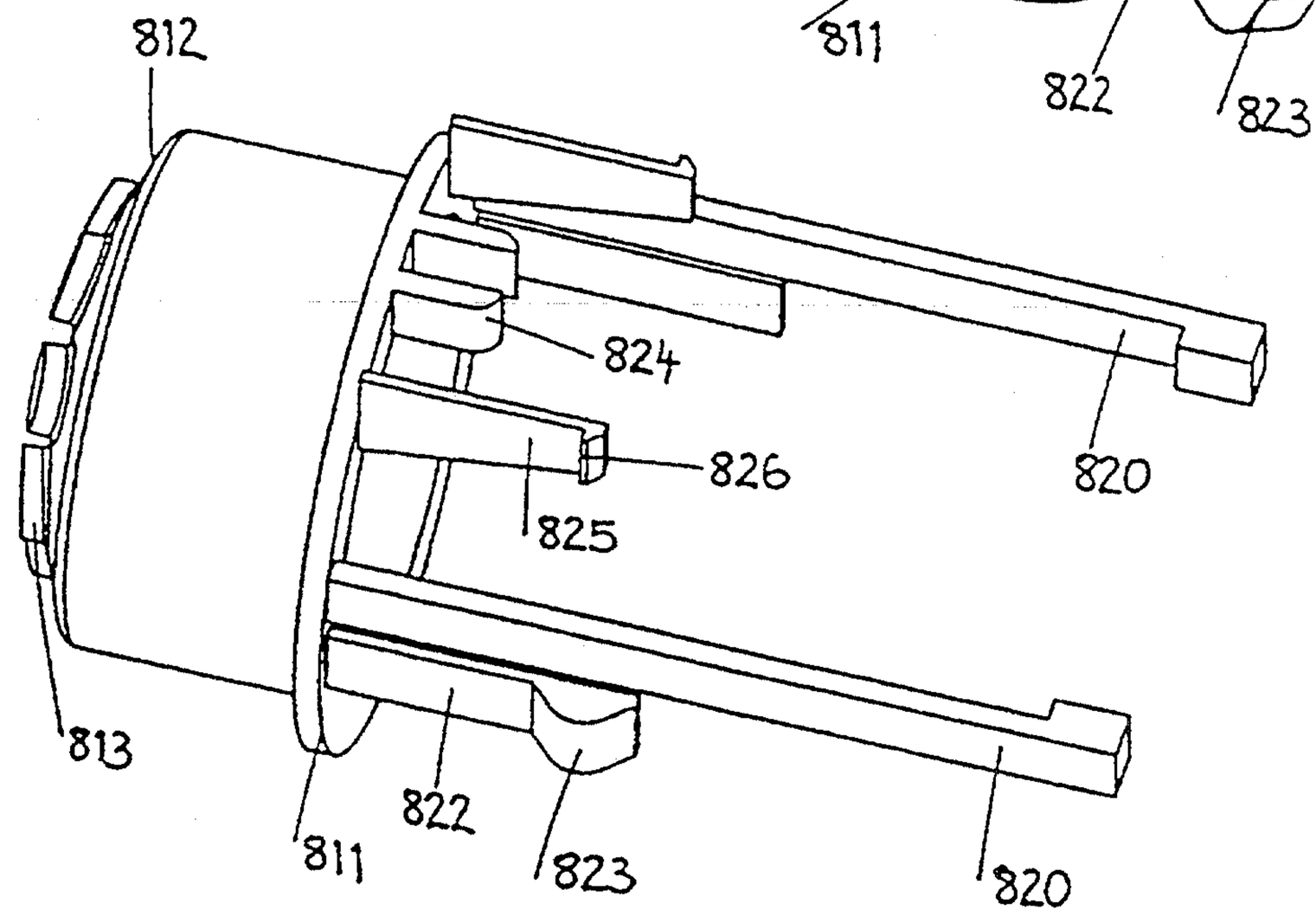


Fig. 10B

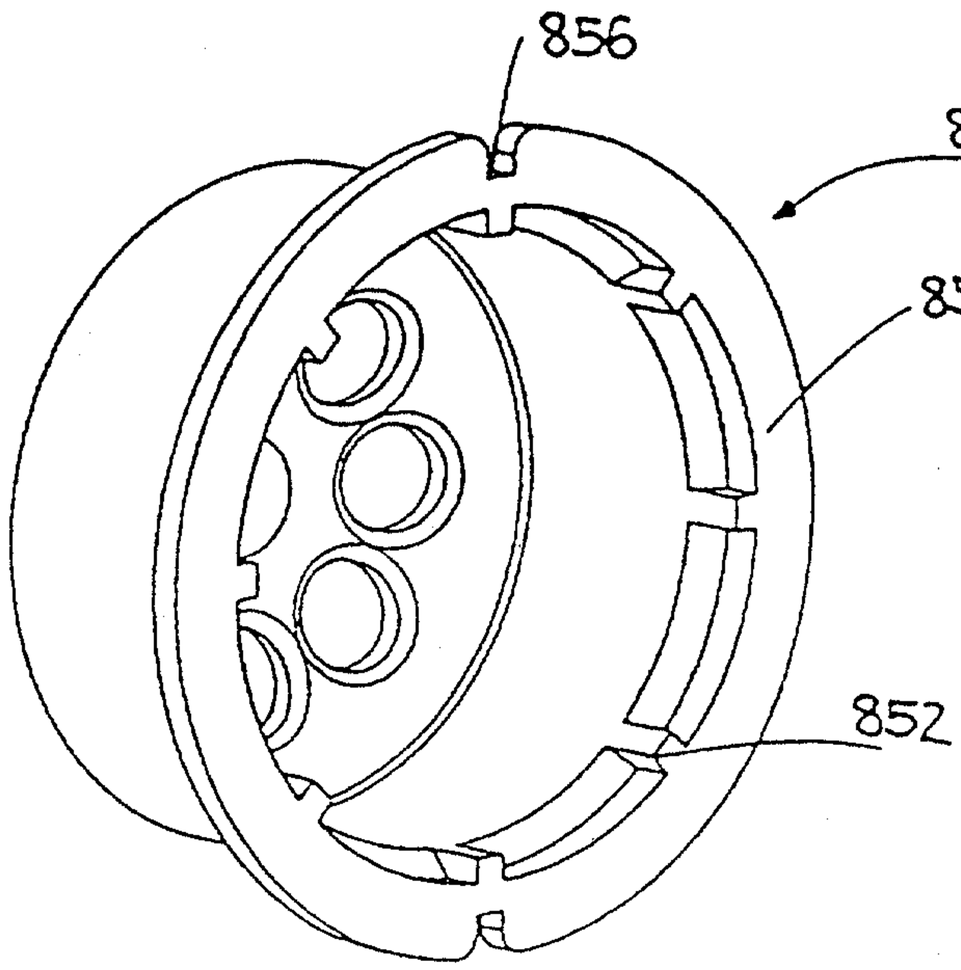


Fig. 11A

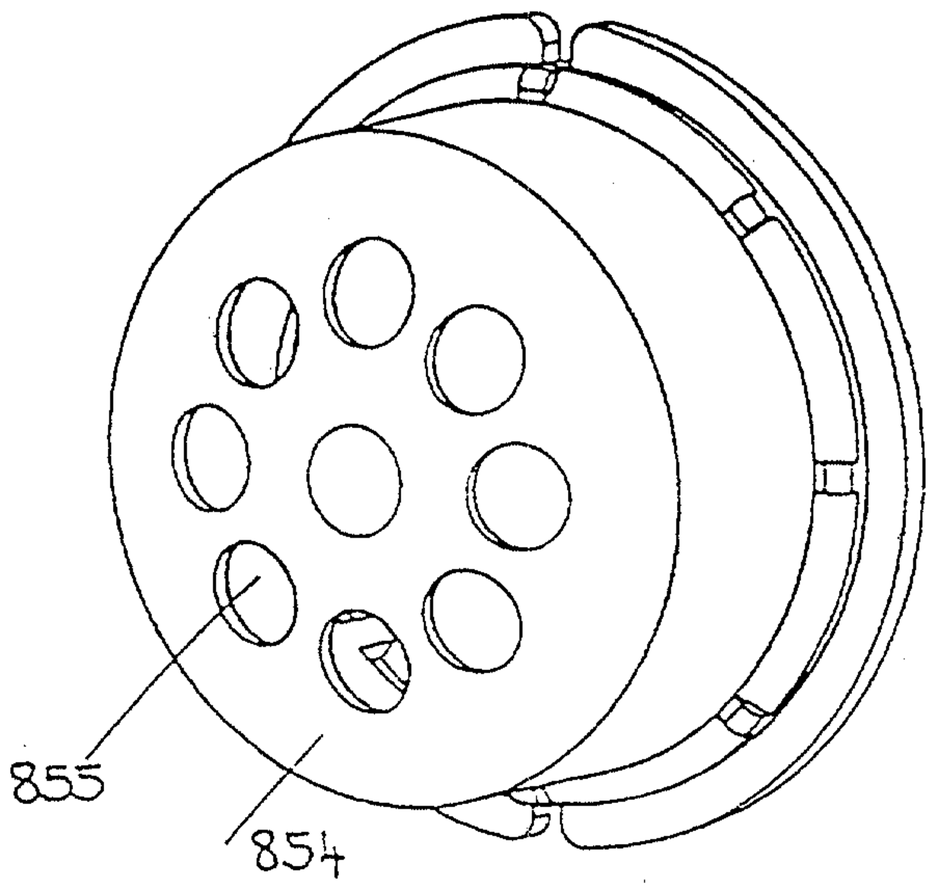


Fig. 11B

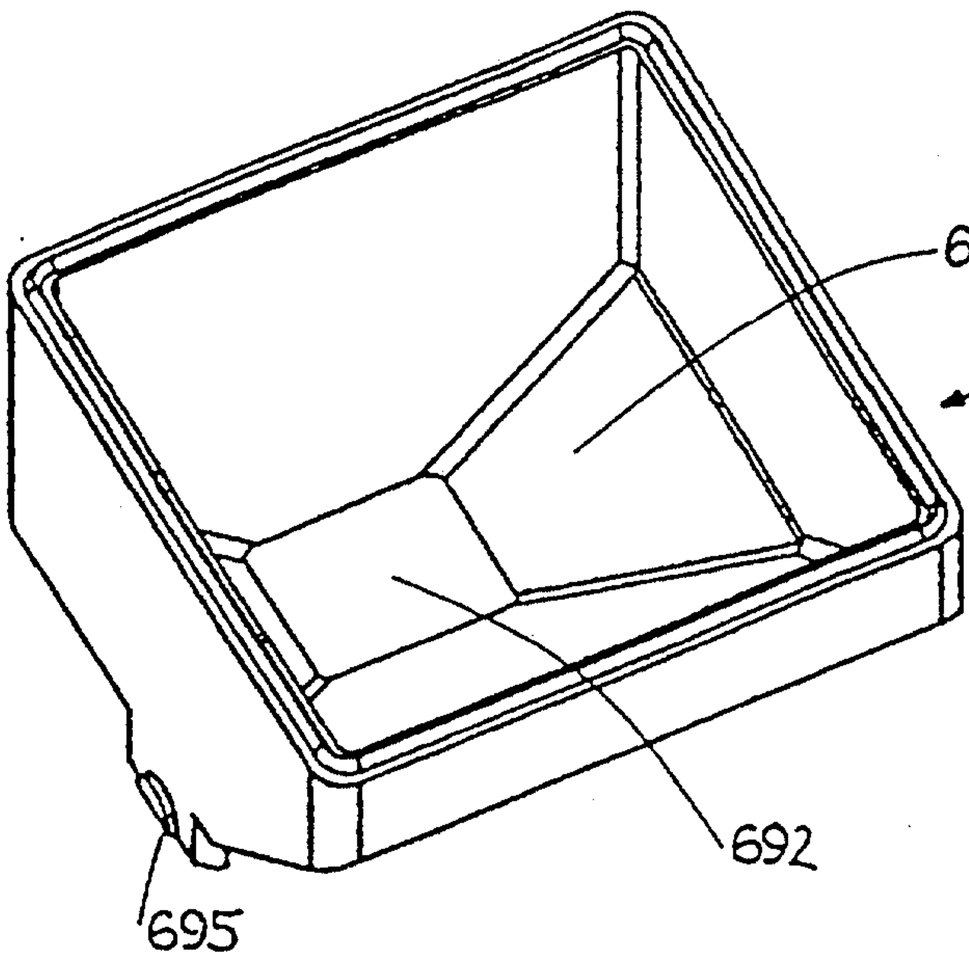


Fig. 12A

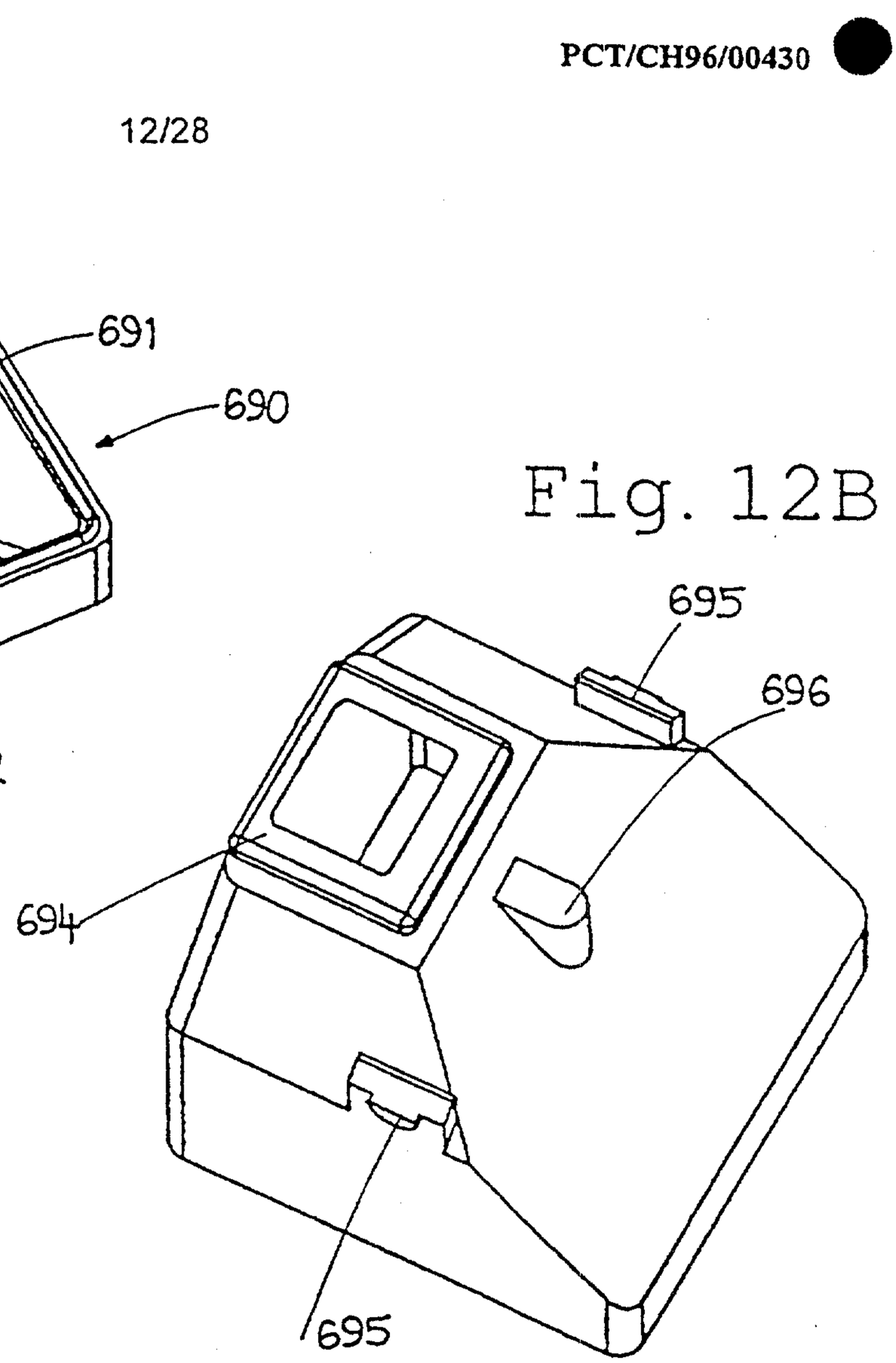


Fig. 12B

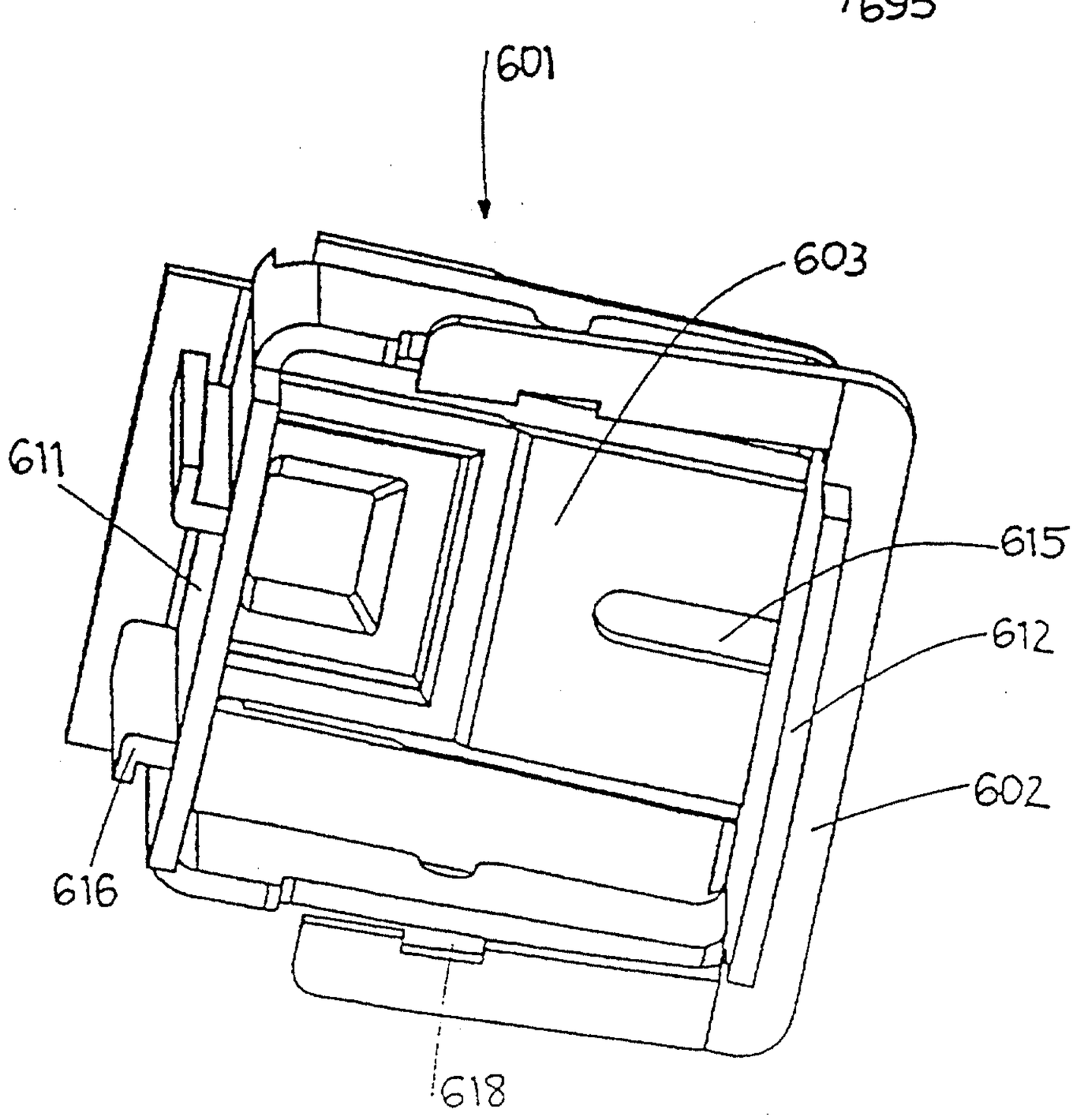


Fig. 13A

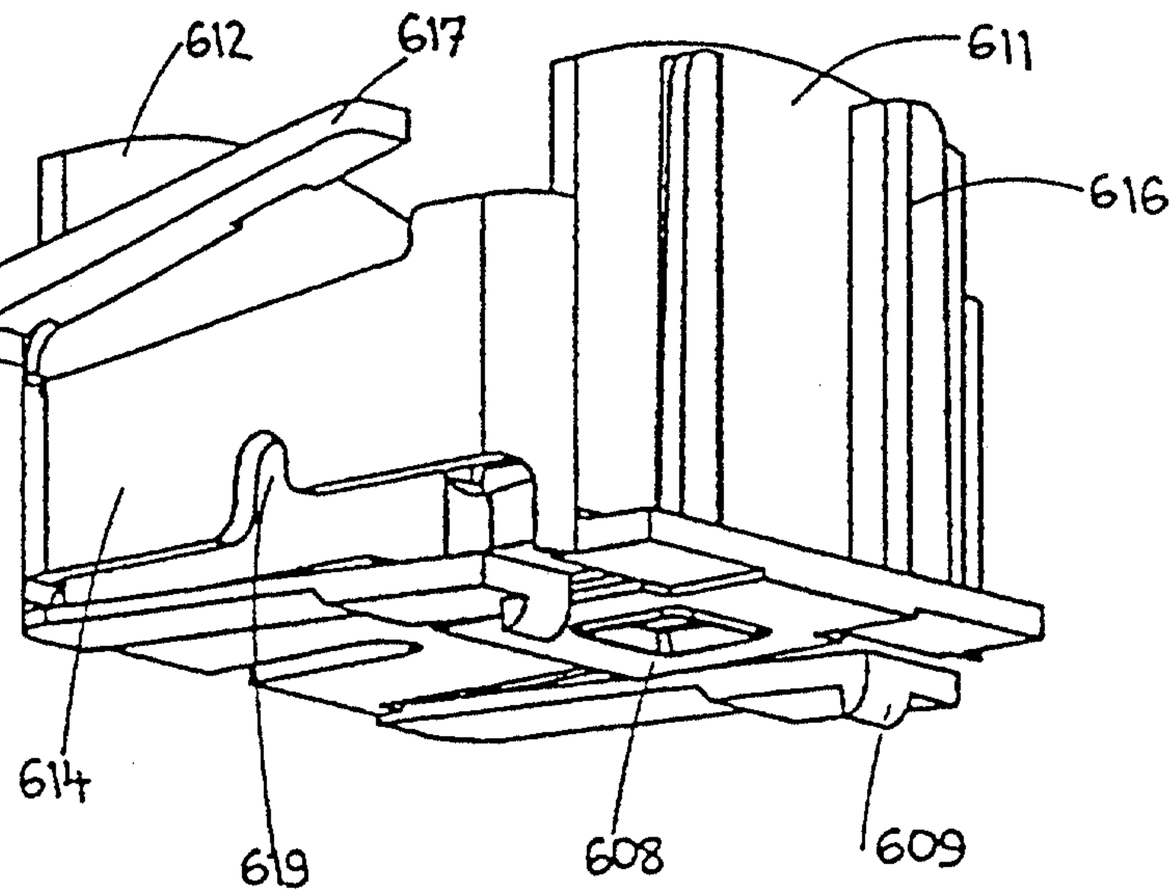


Fig. 13B

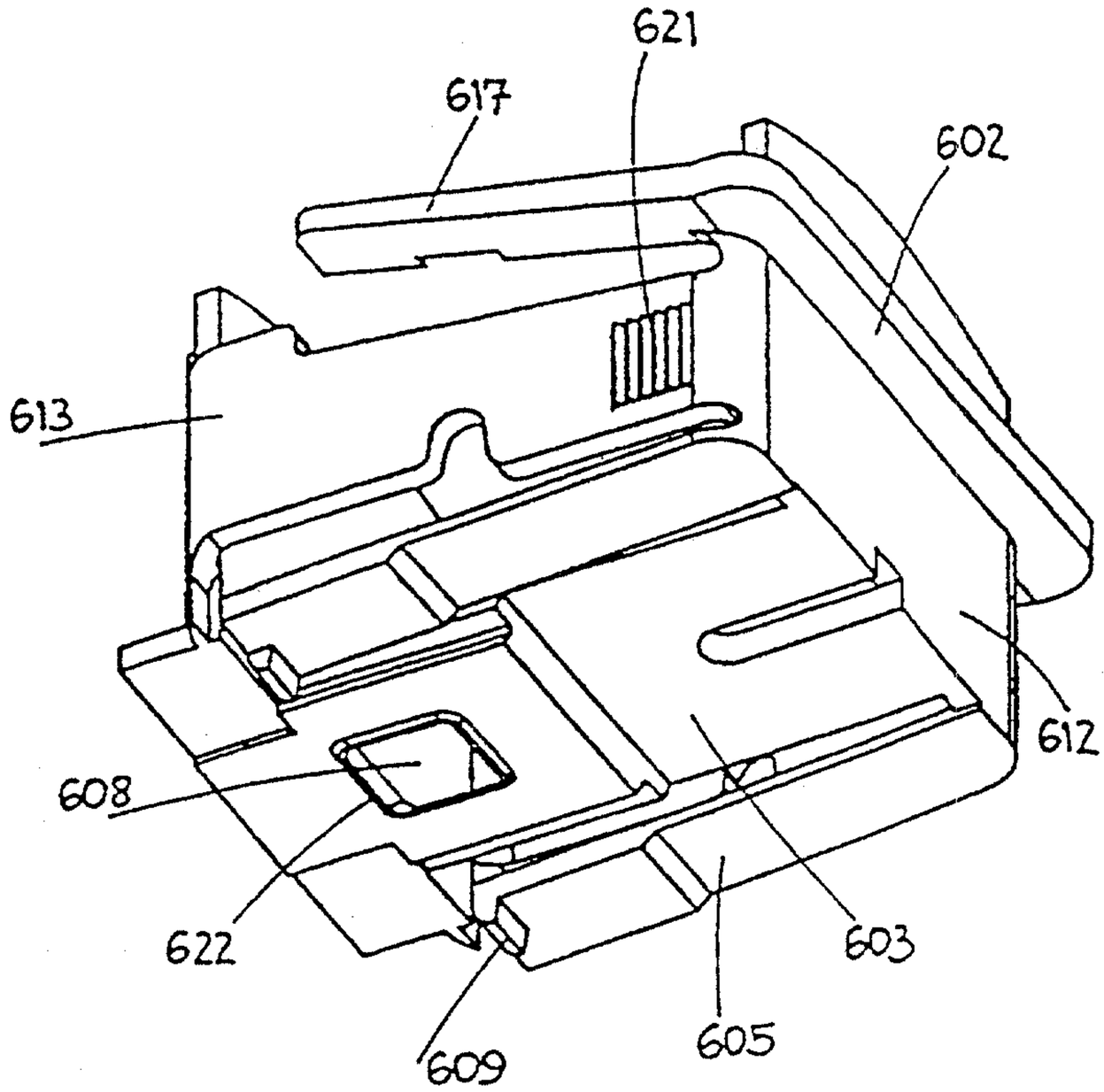


Fig. 13C

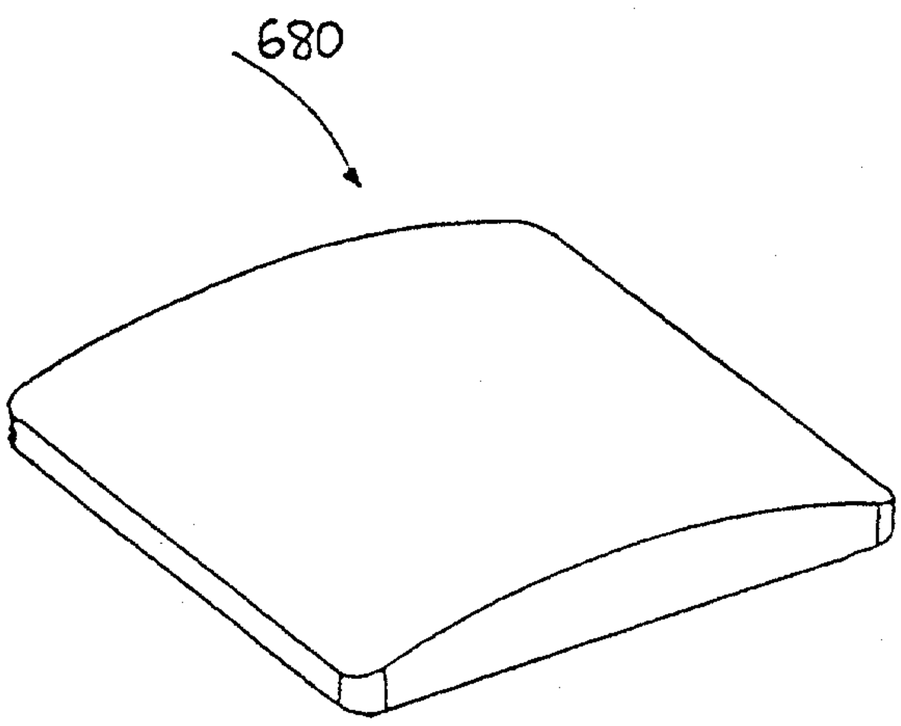


Fig. 14A

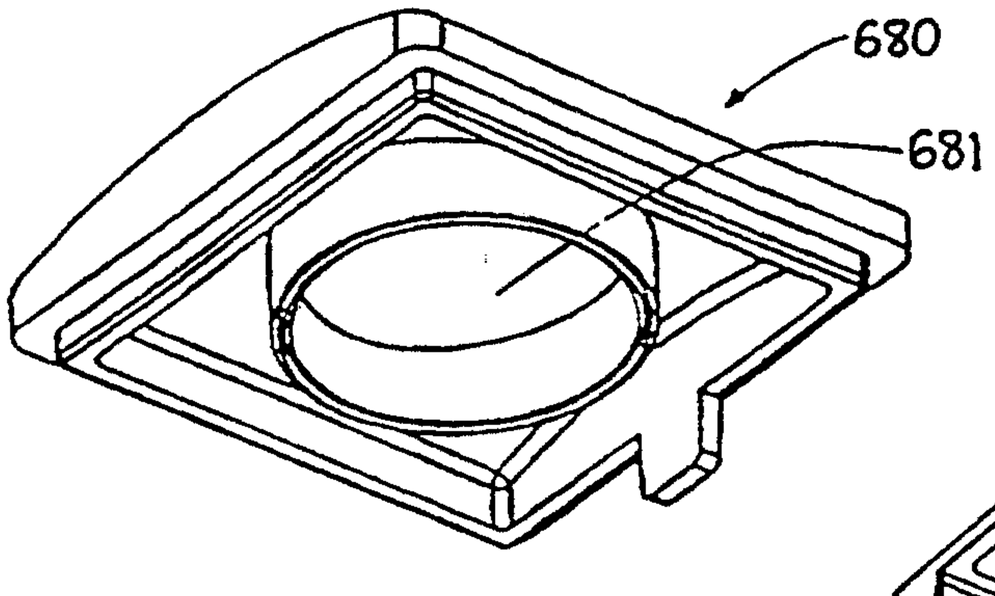


Fig. 14B

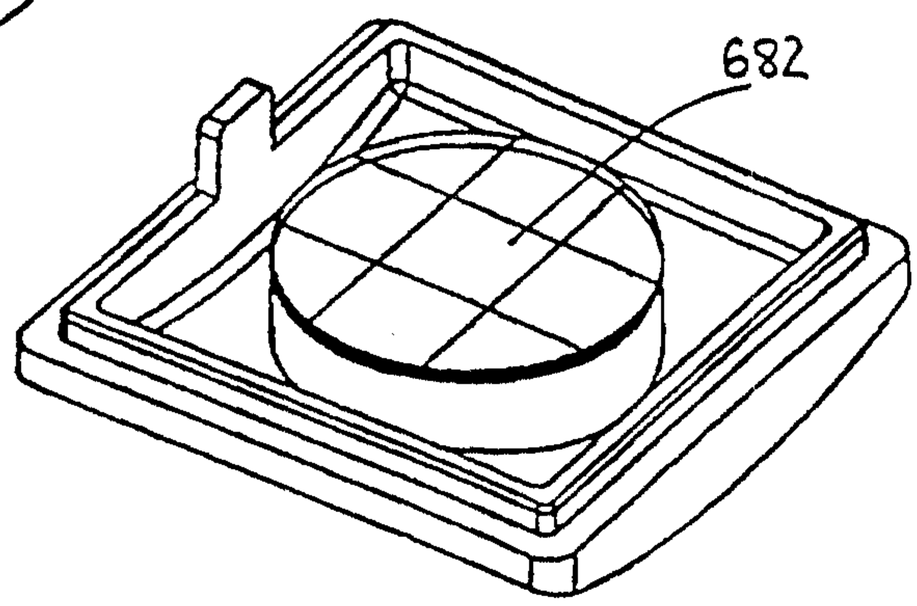


Fig. 14C

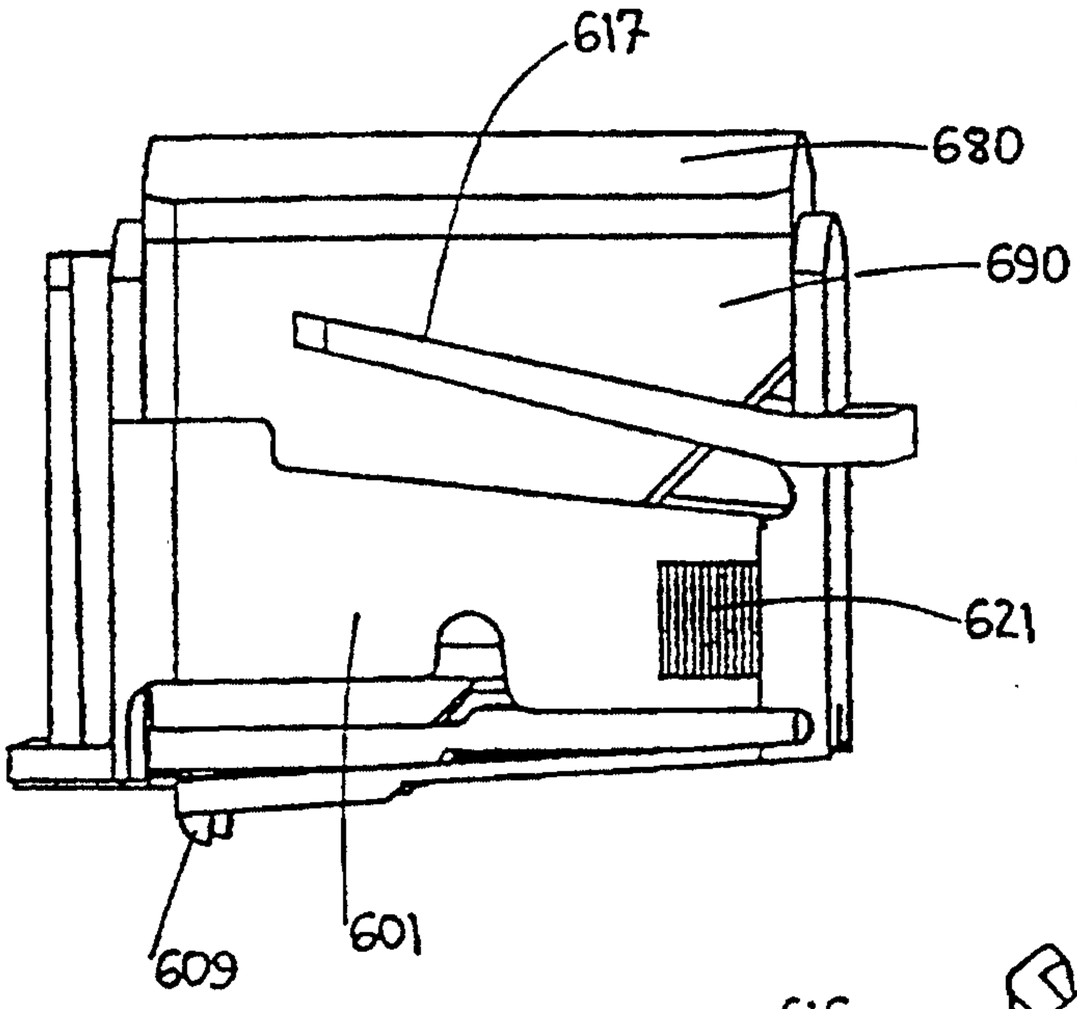


Fig. 15A

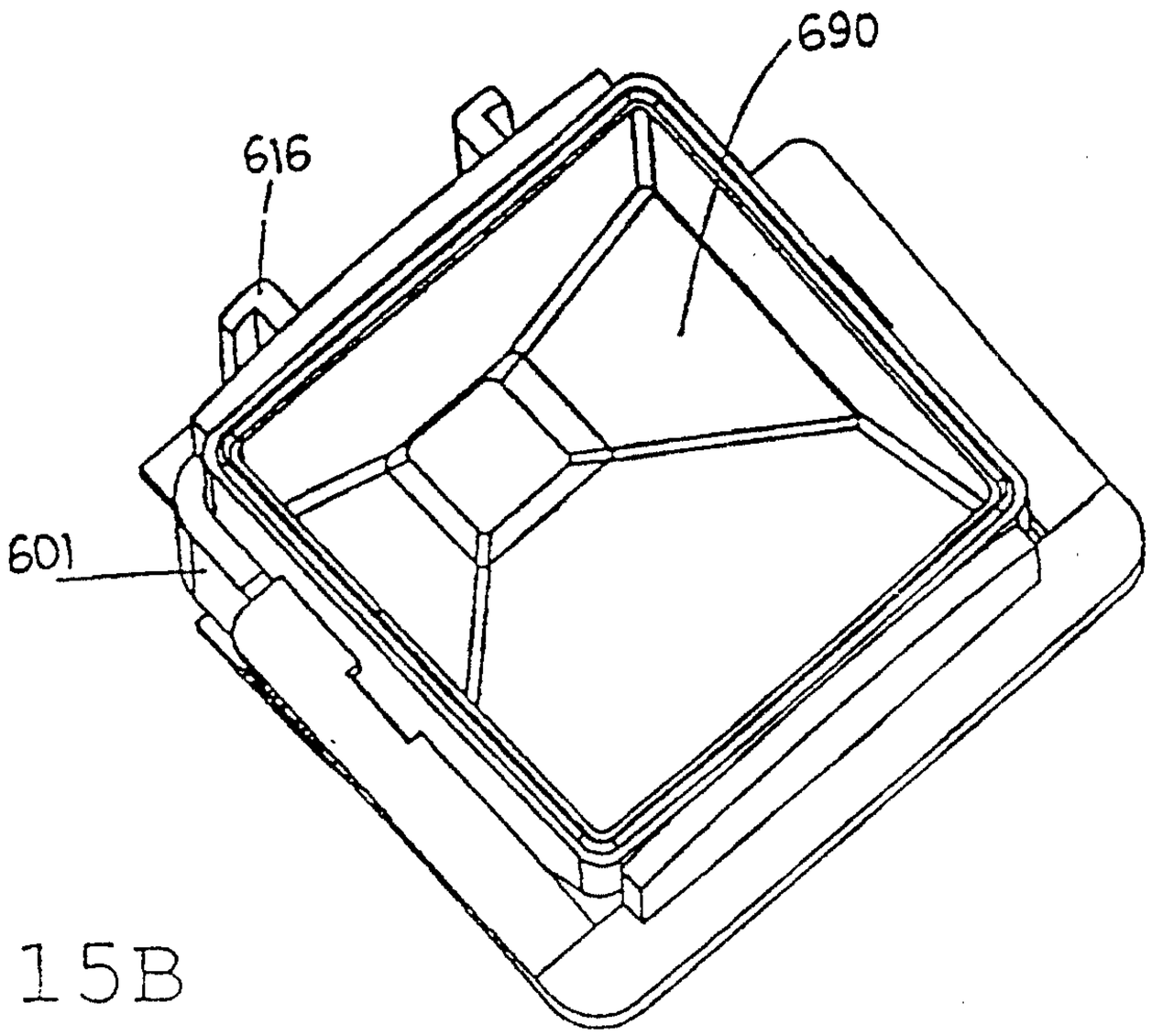


Fig. 15B

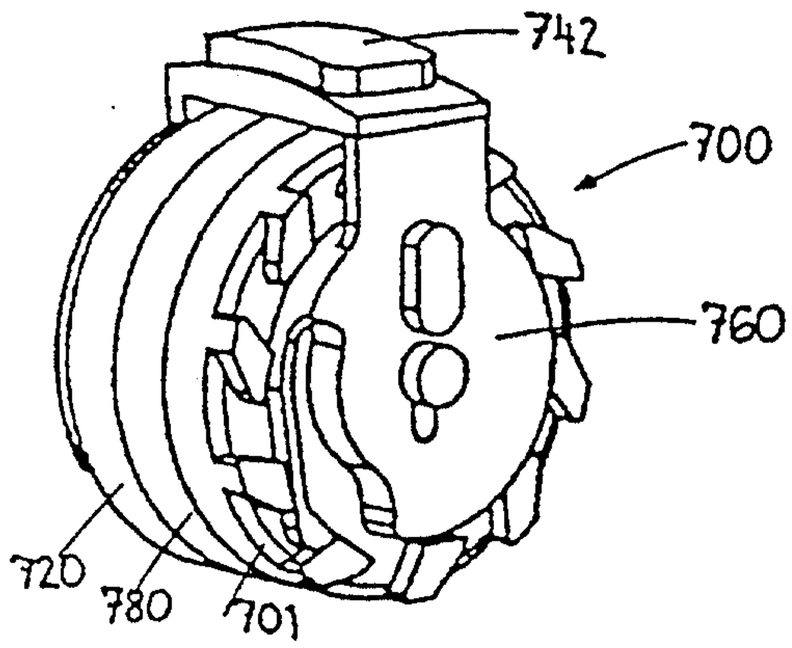


Fig.16A

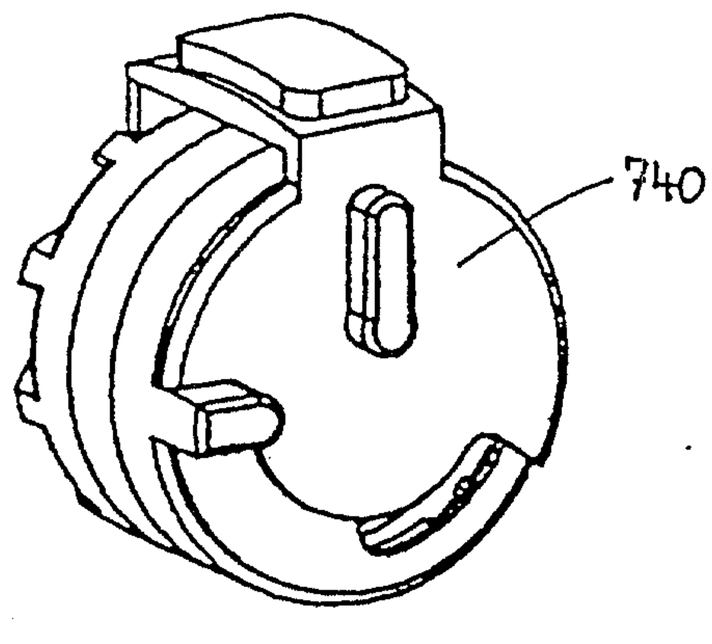


Fig.16B

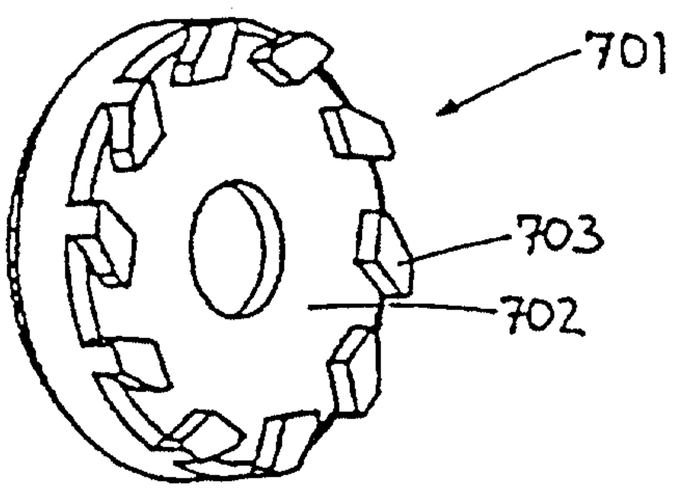


Fig.16C

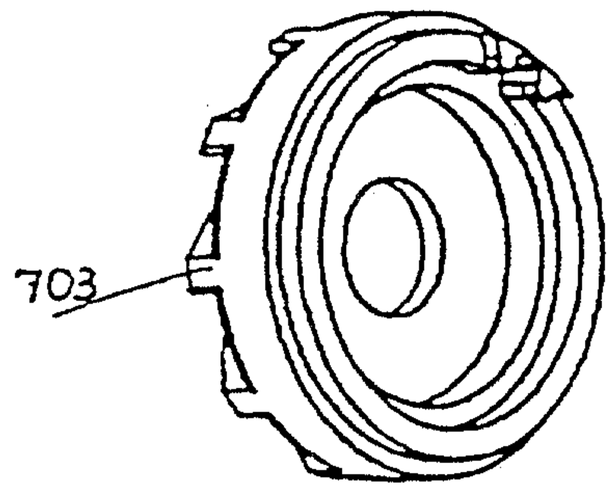


Fig.16D

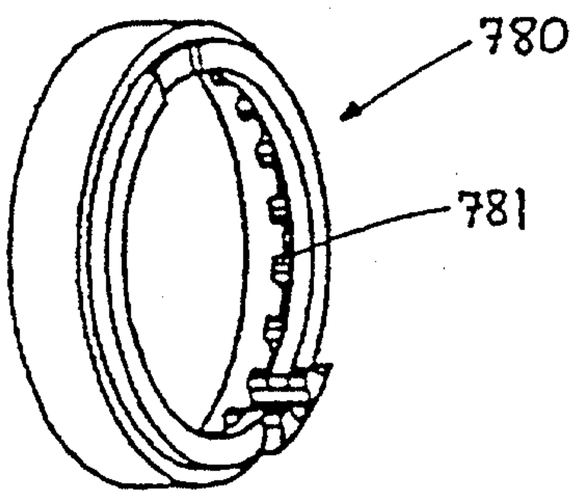


Fig.16E

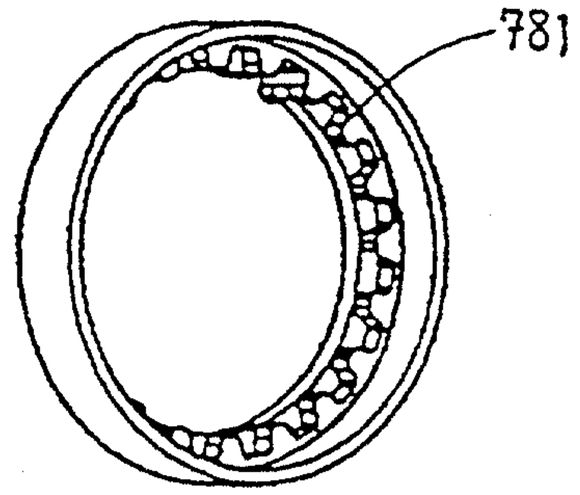


Fig.16F

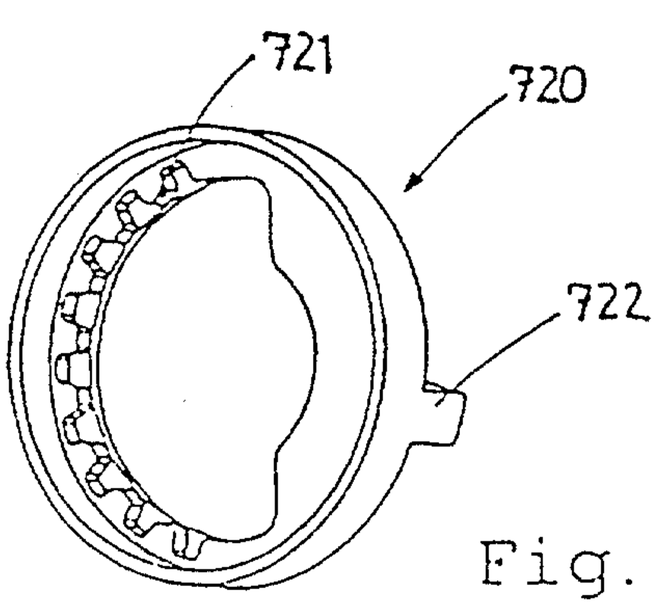


Fig.16G

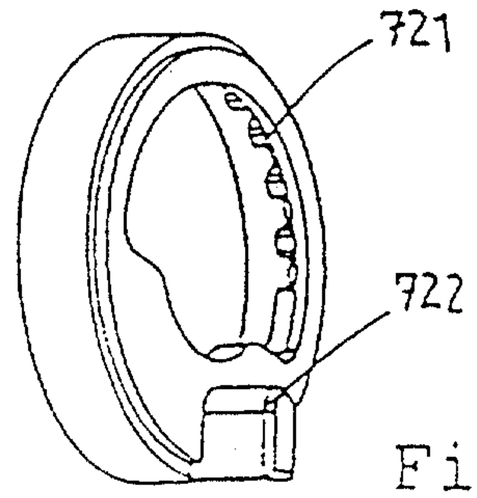


Fig.16H

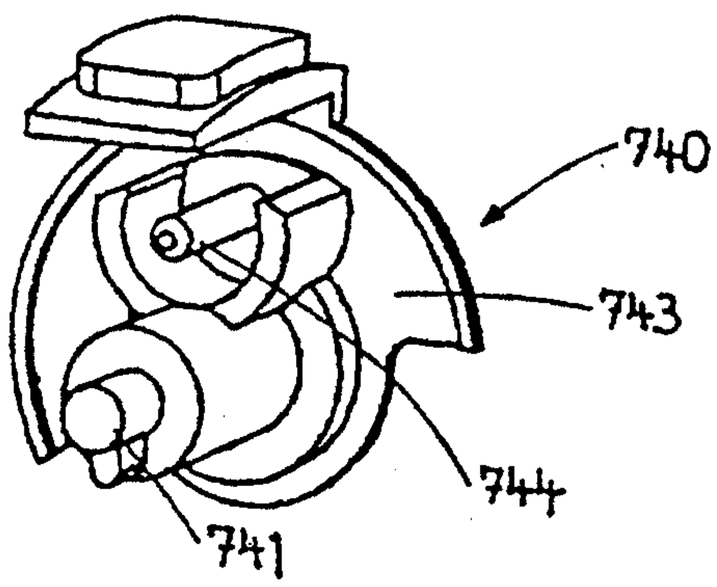


Fig.16I

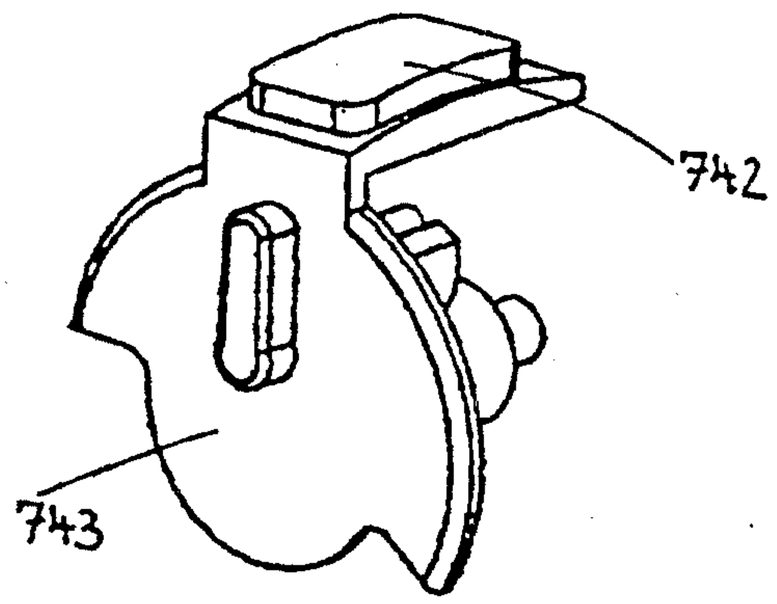


Fig.16J

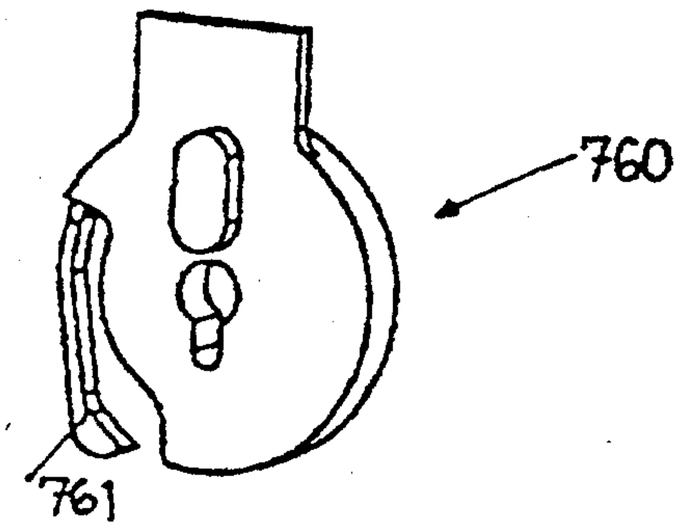


Fig.16K

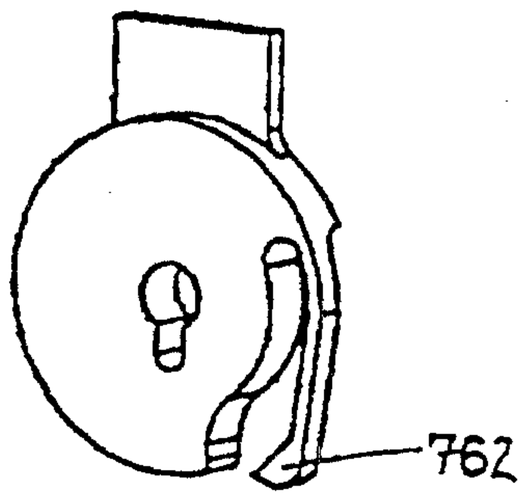


Fig.16L

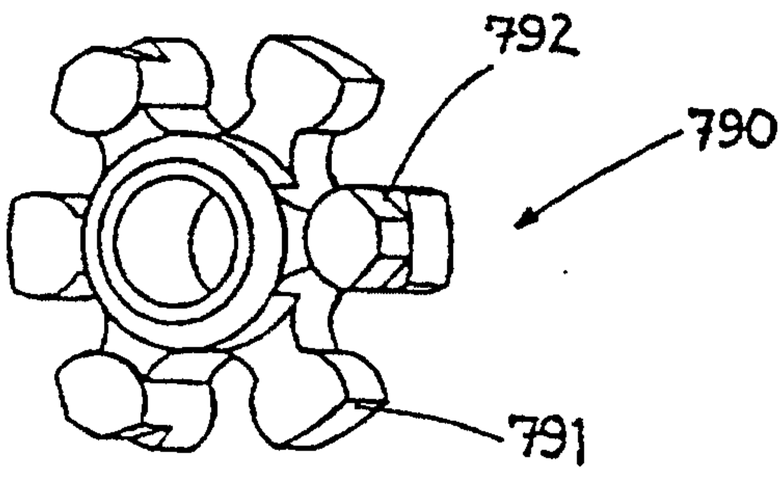


Fig.16M

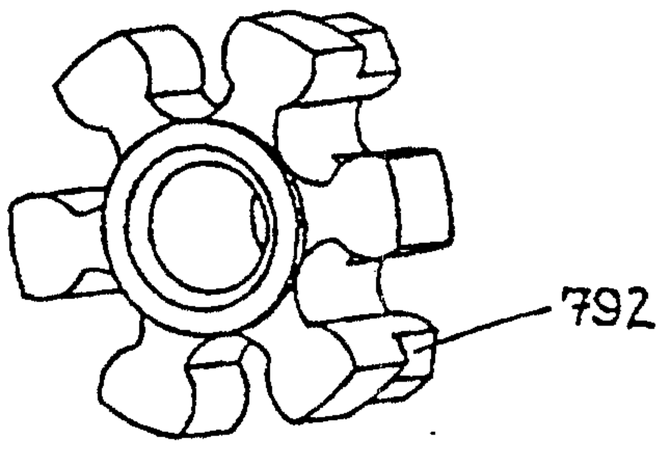


Fig.16N

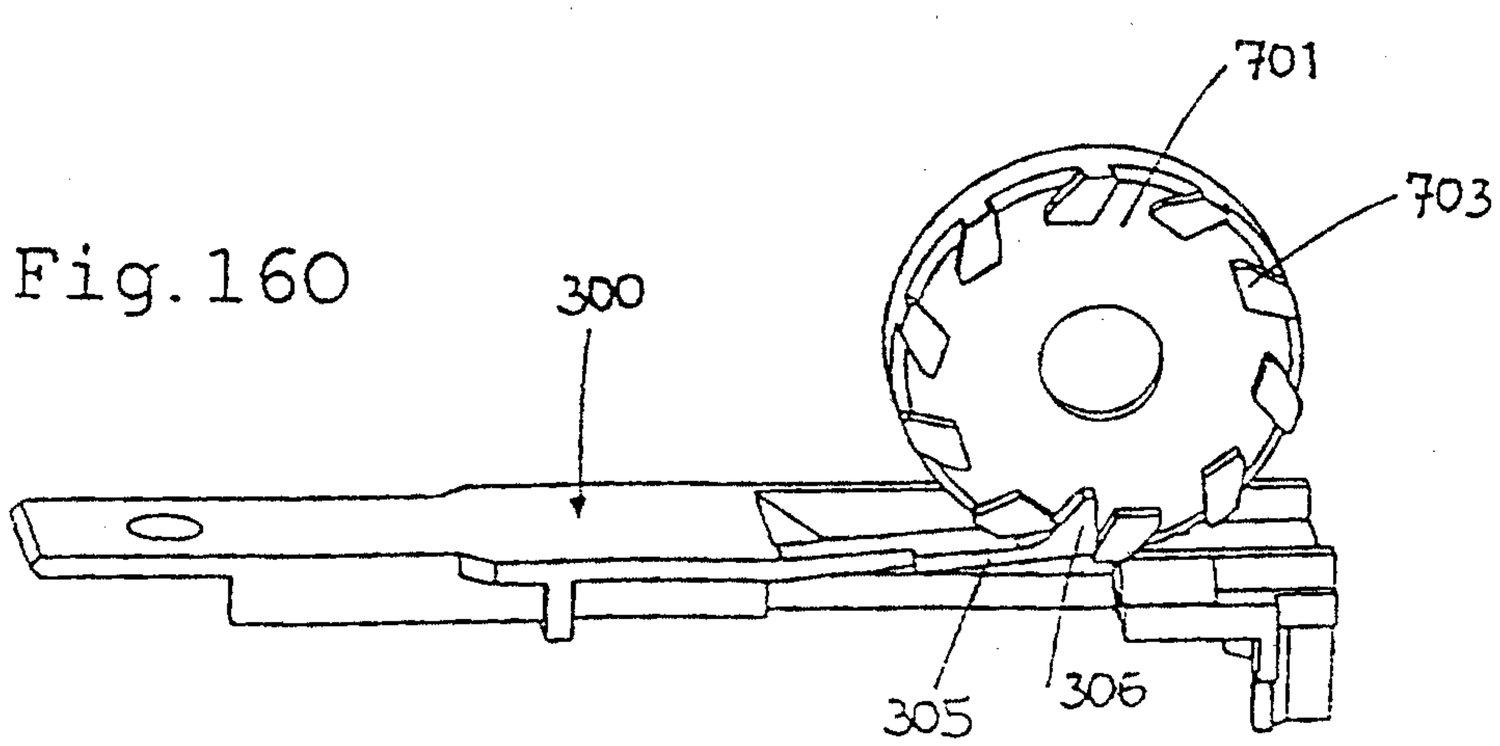


Fig.160

Fig. 17A

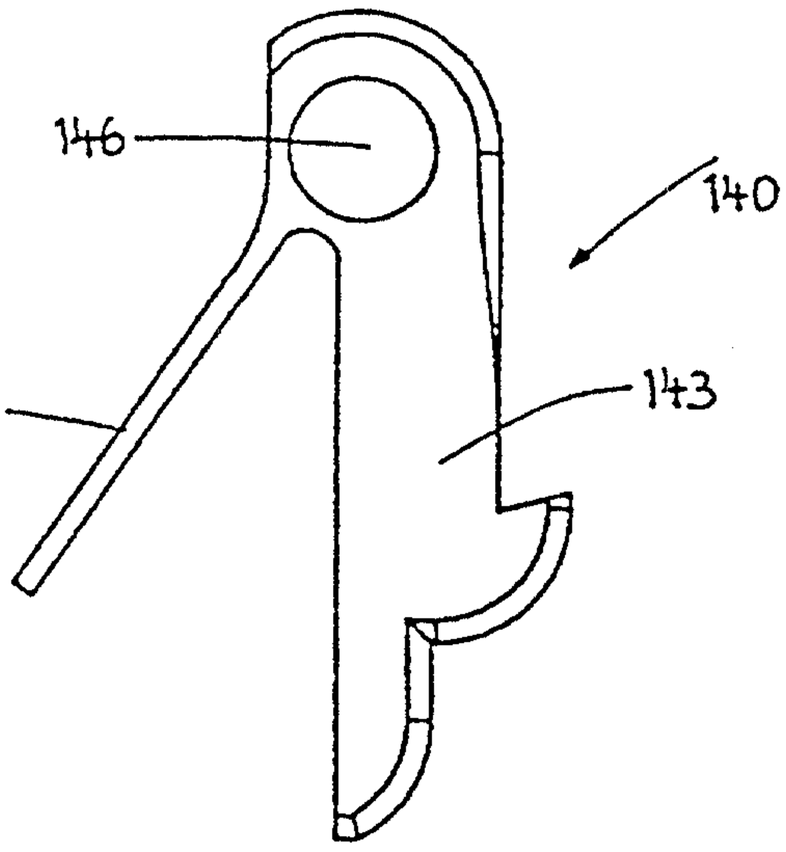


Fig. 17B

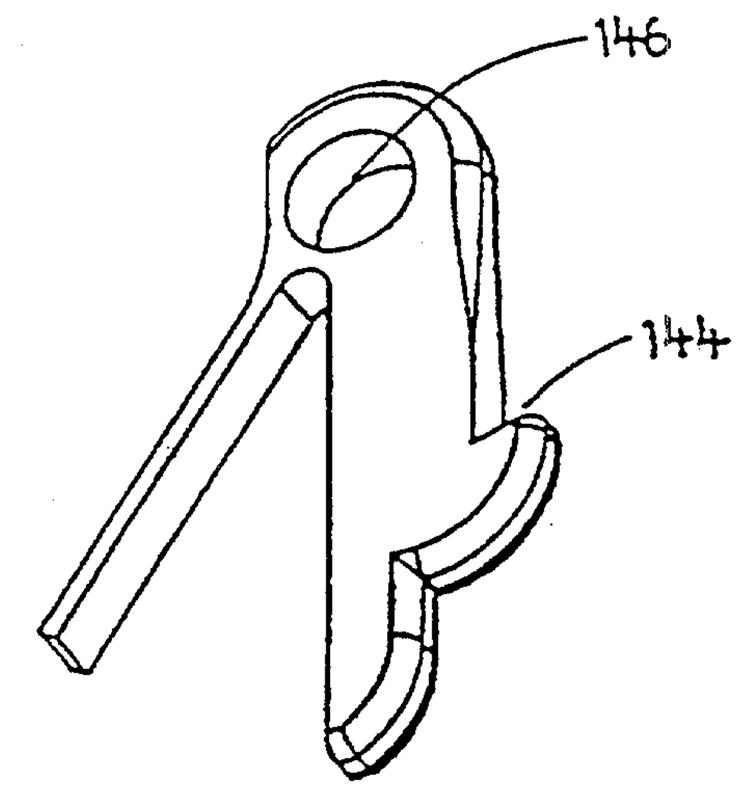
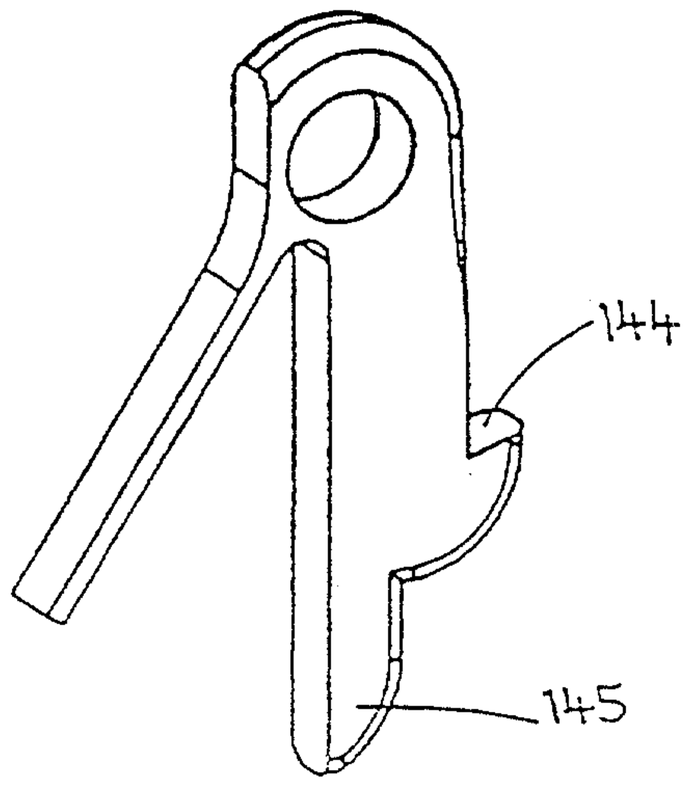


Fig. 17C



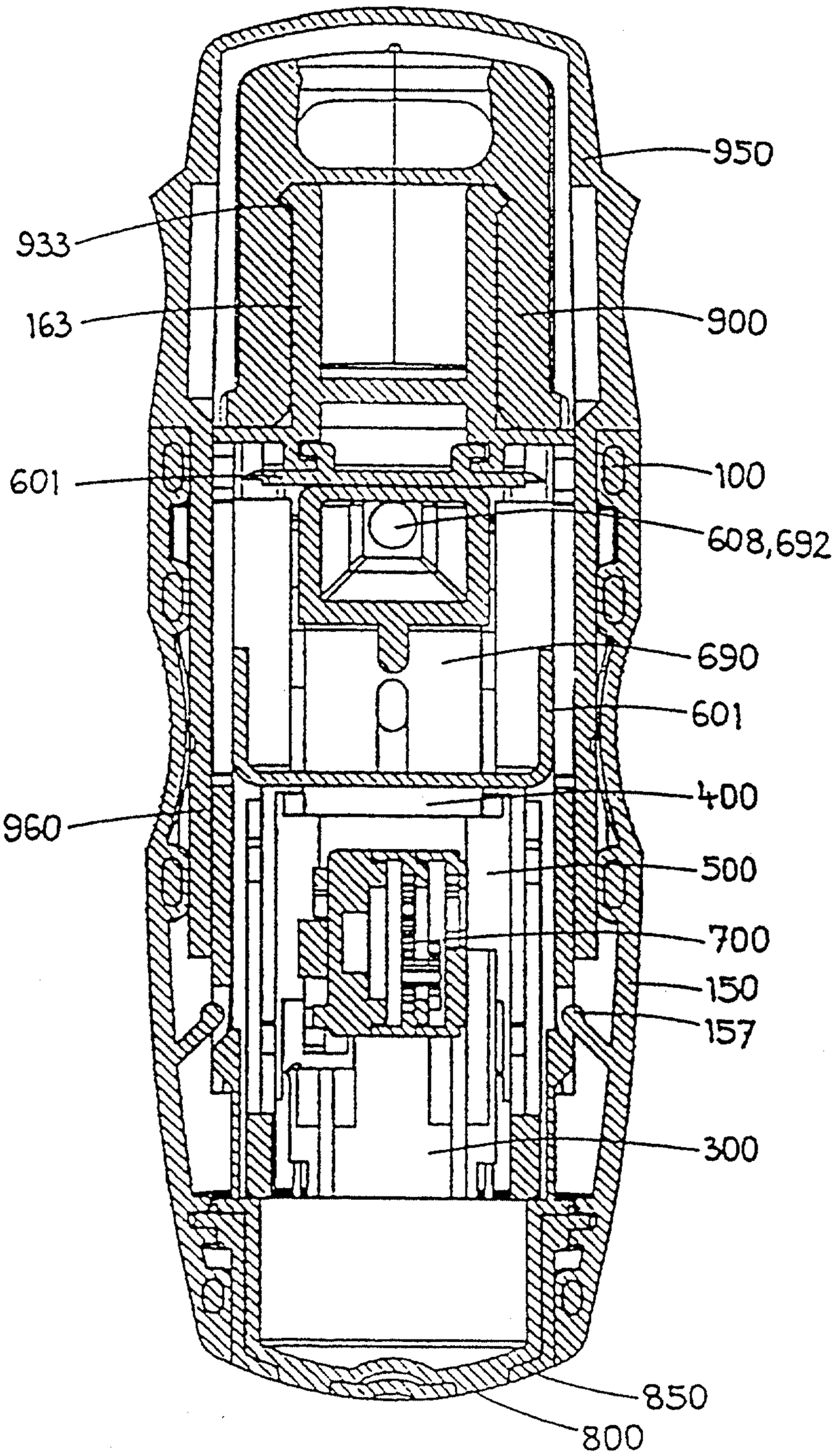

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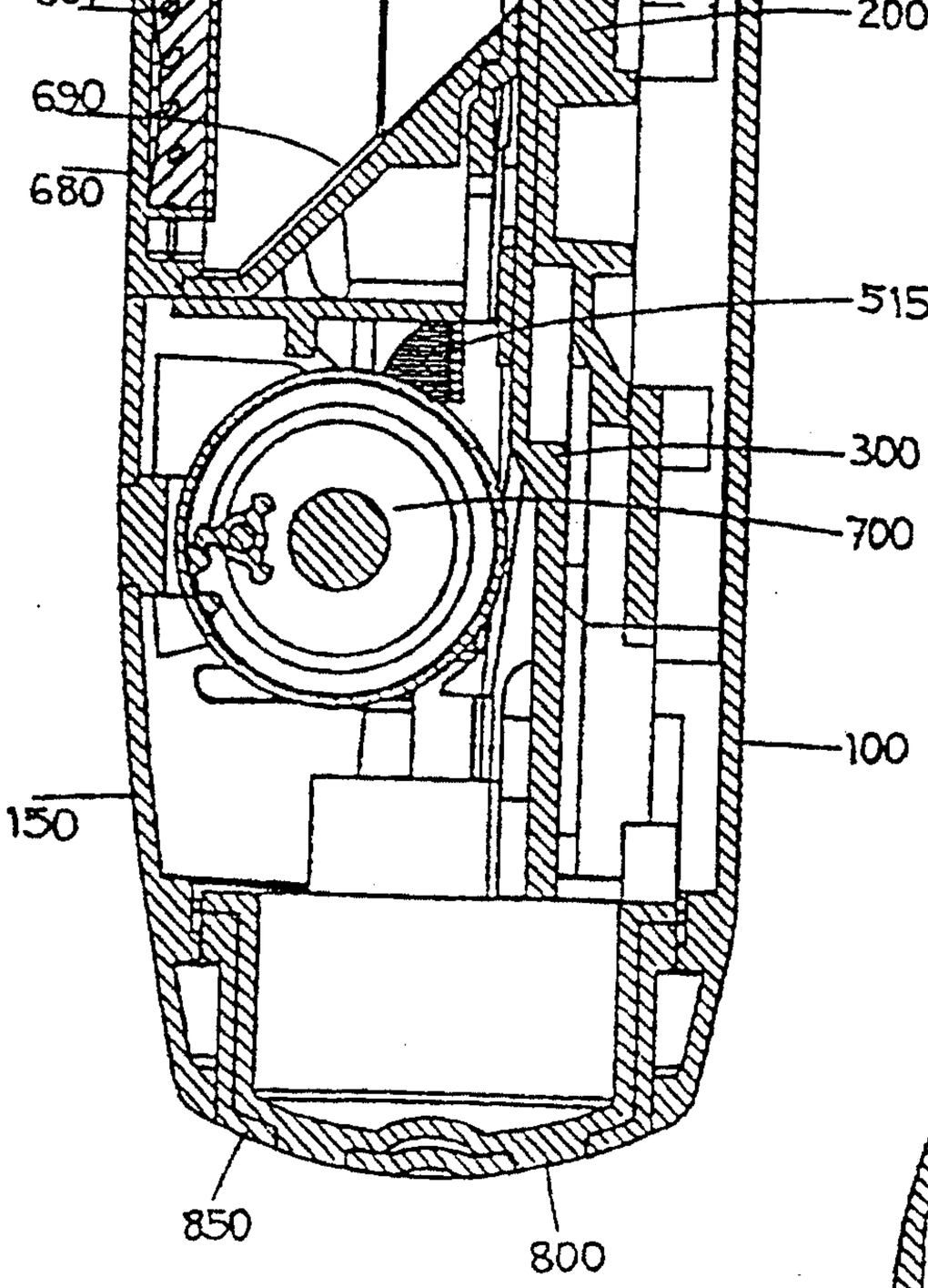
Fig. 18A

Fig. 18B



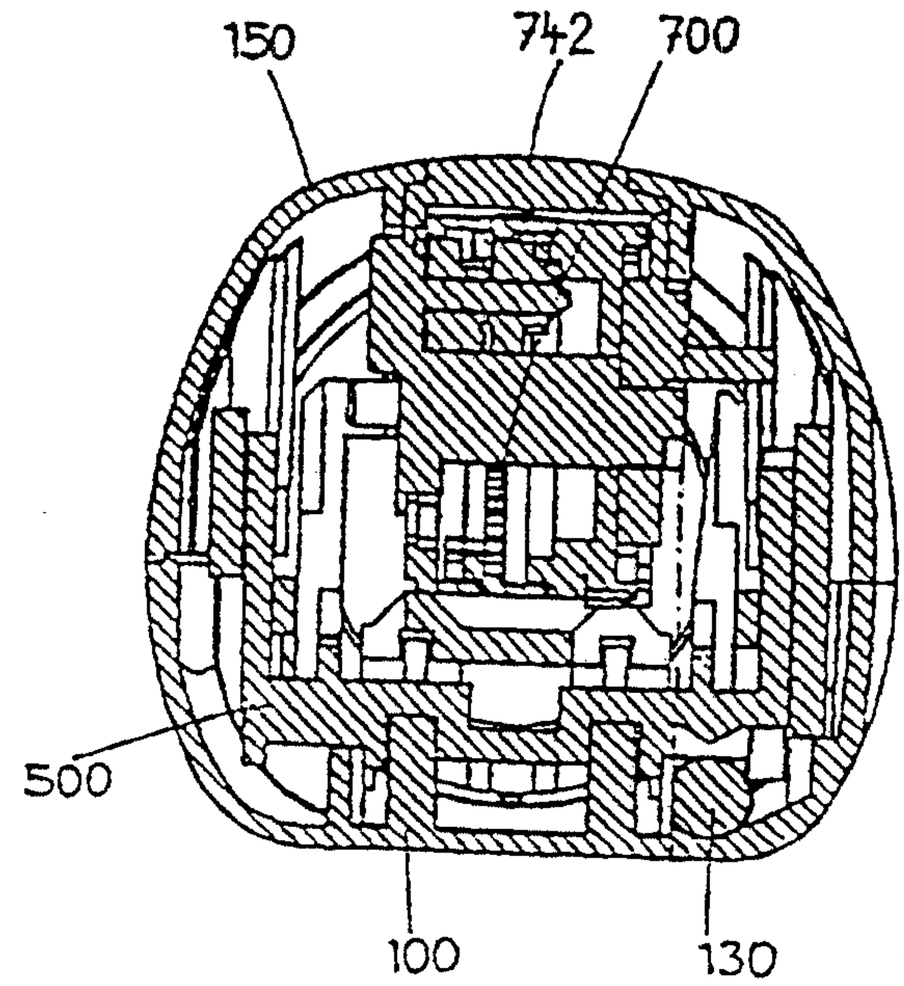


Fig. 18C

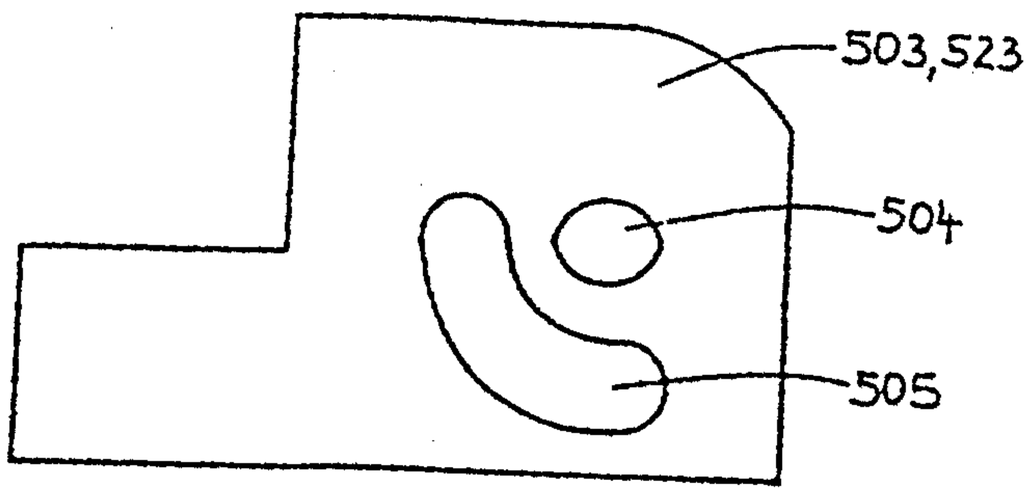


Fig. 19A

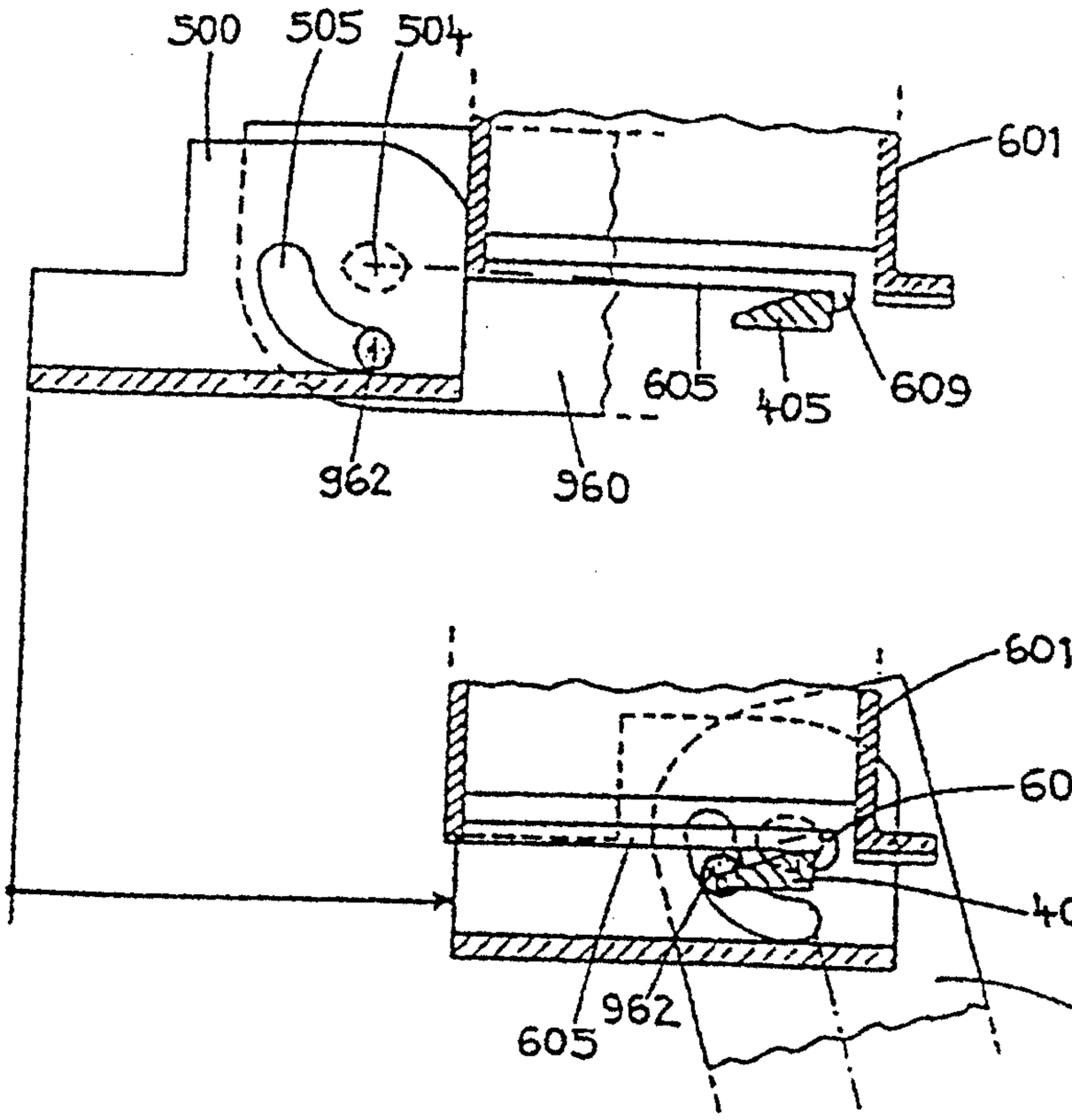


Fig. 19B

Fig. 19C

Fig. 19D

Fig. 20A

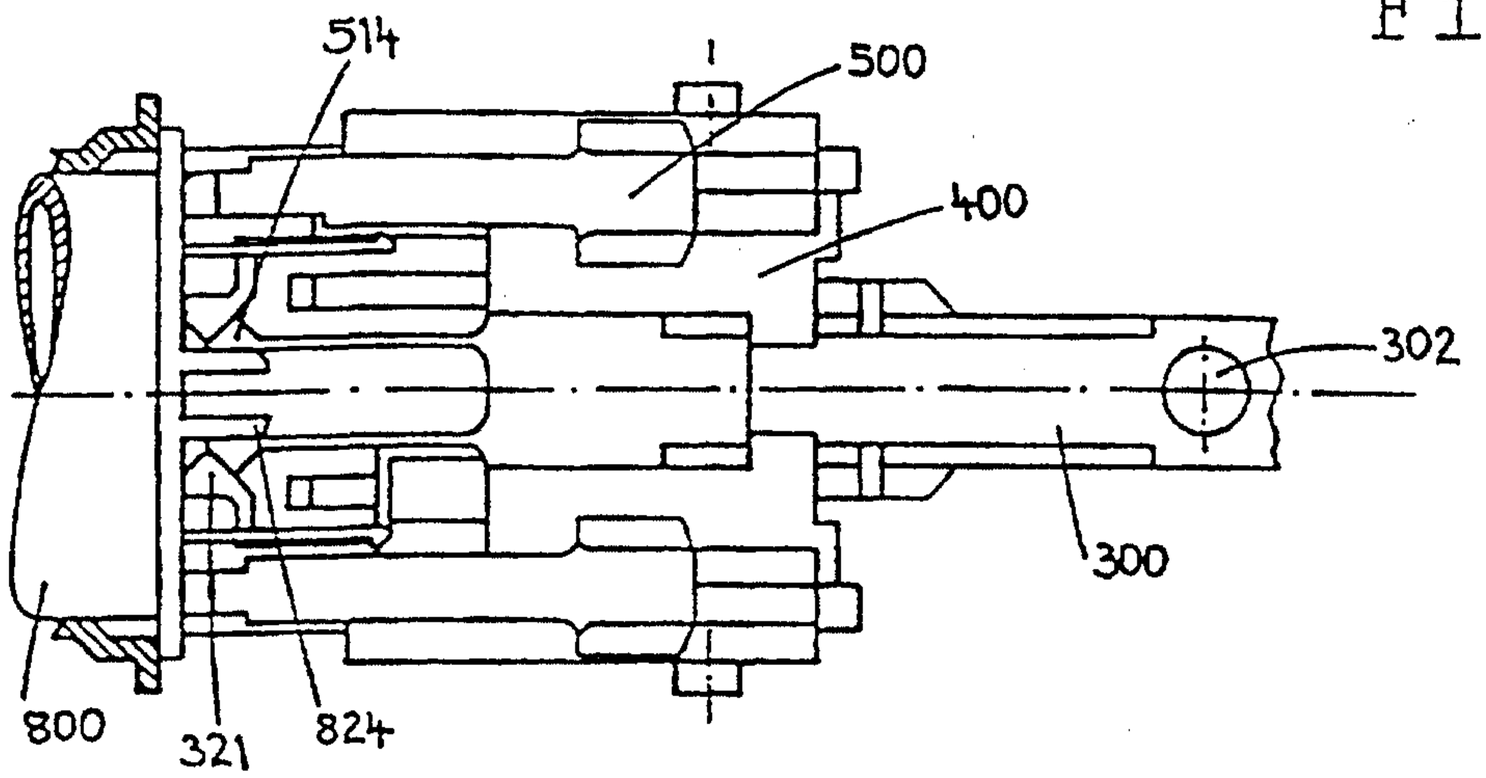
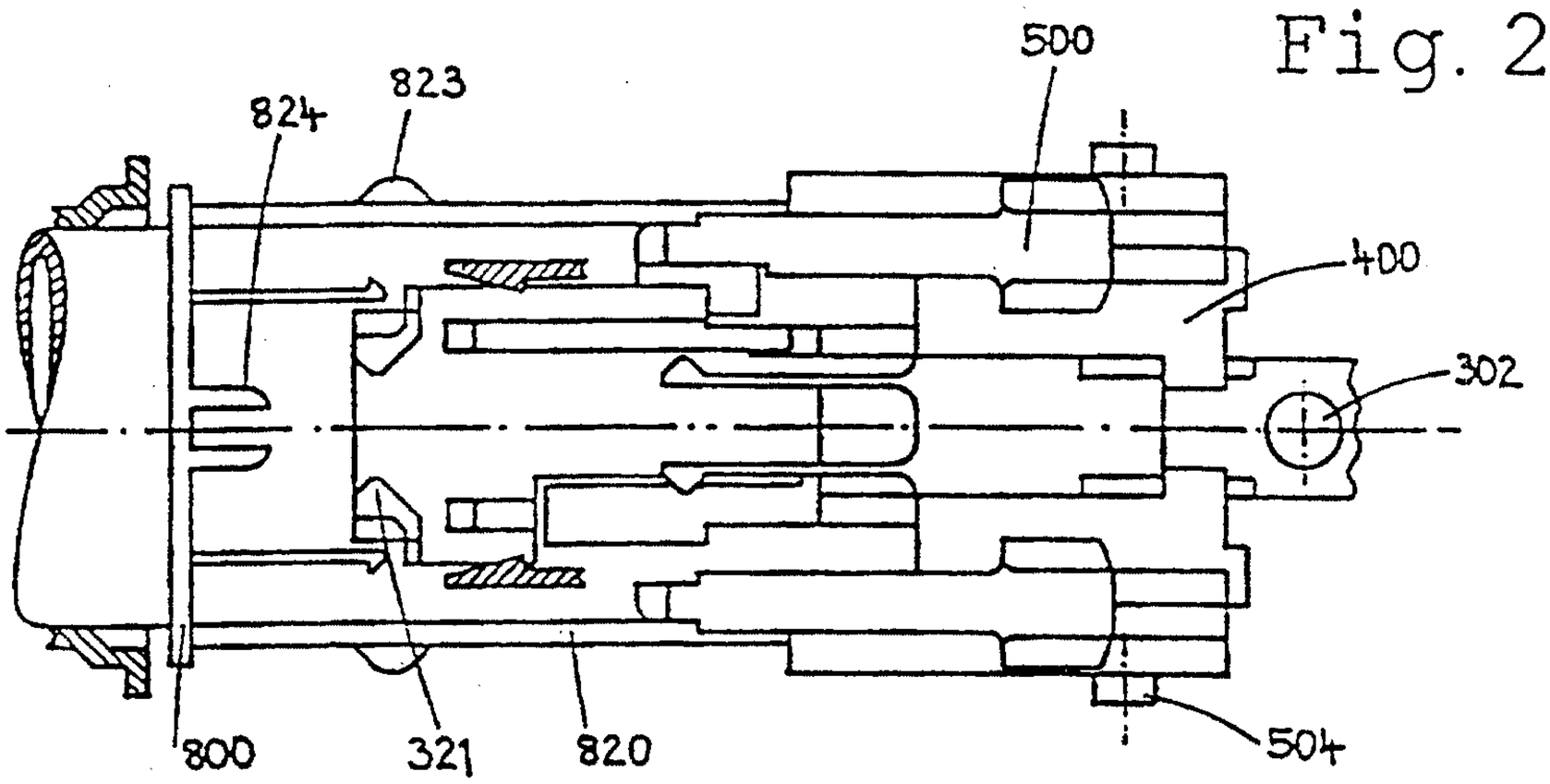


Fig. 20B



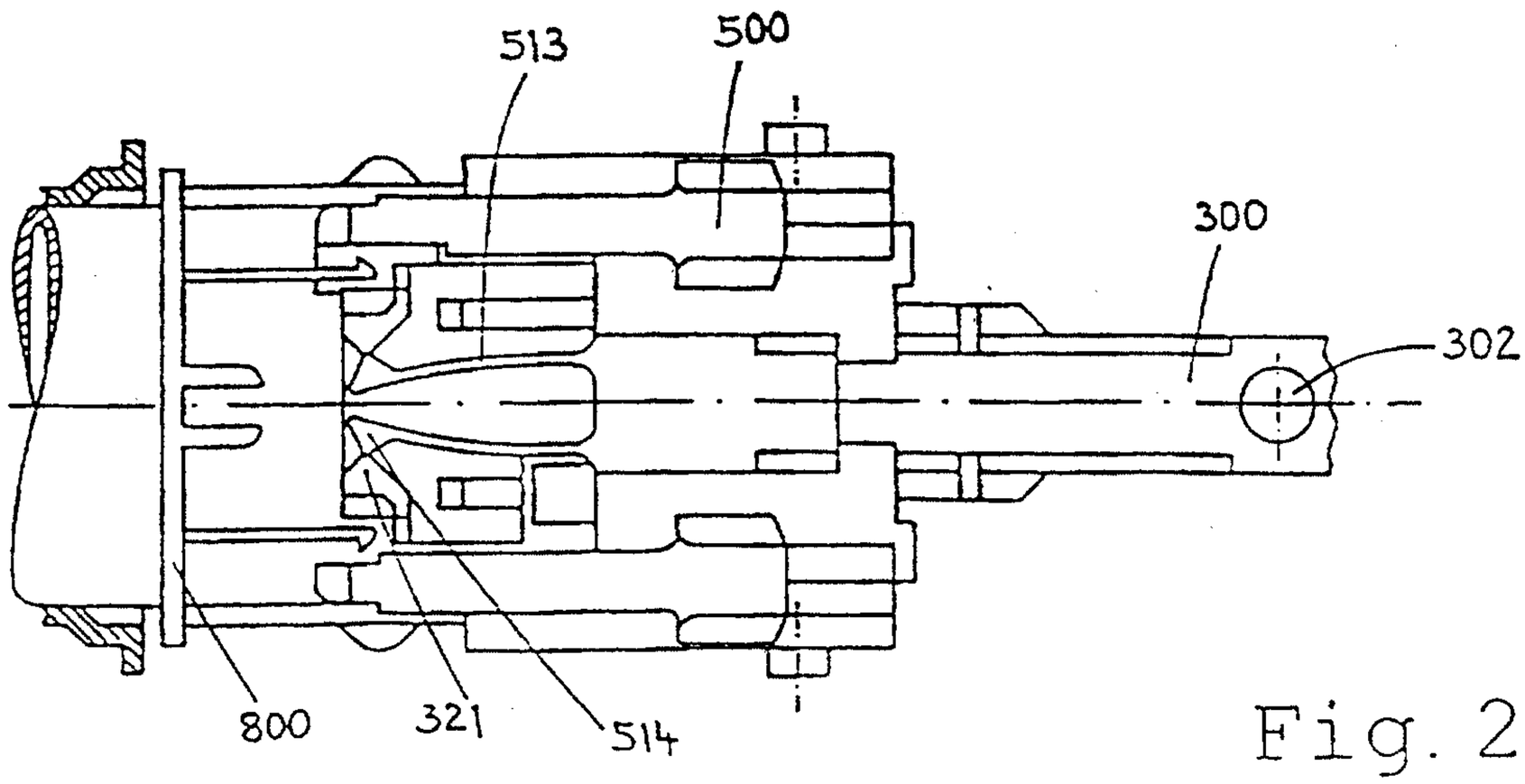


Fig. 20C

Fig. 20D

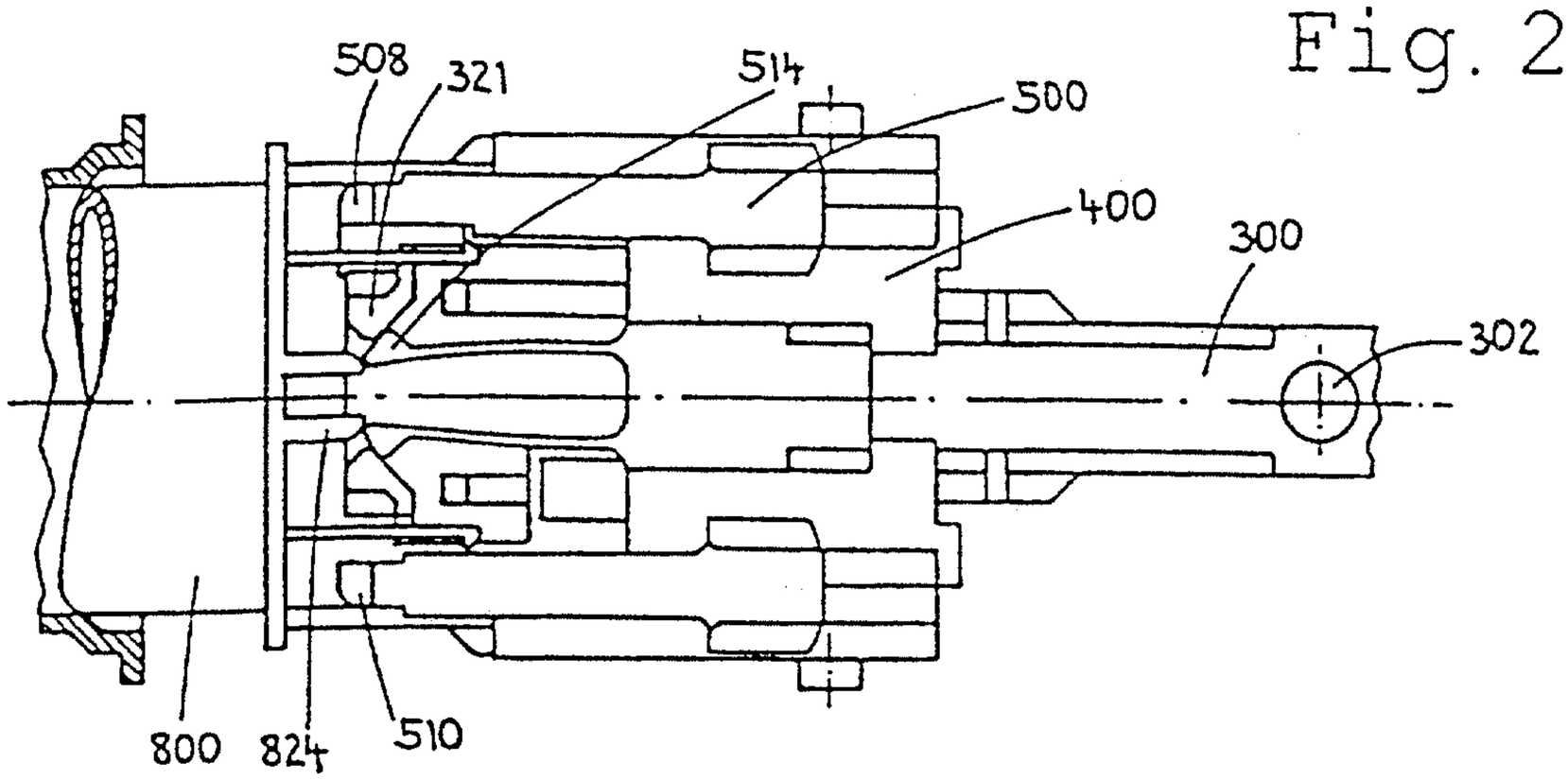


Fig. 20E

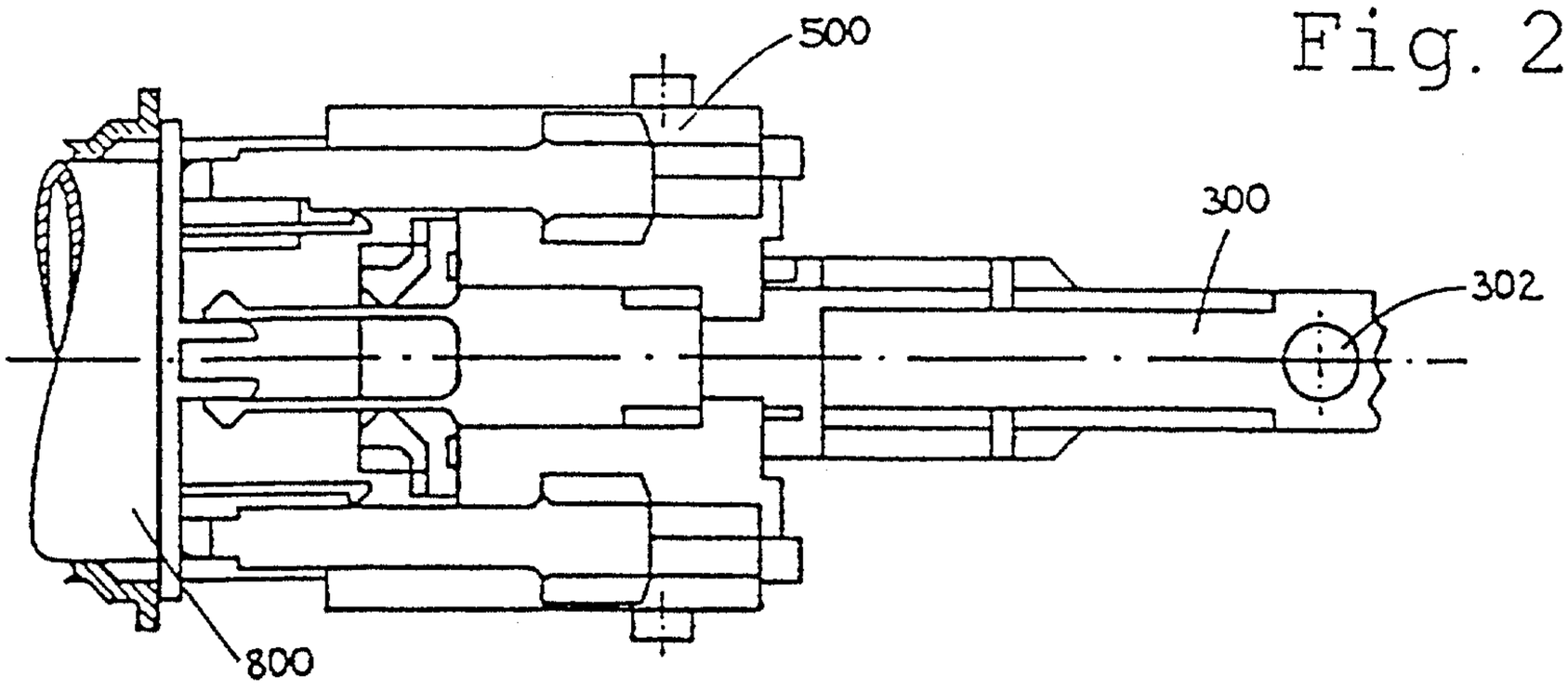
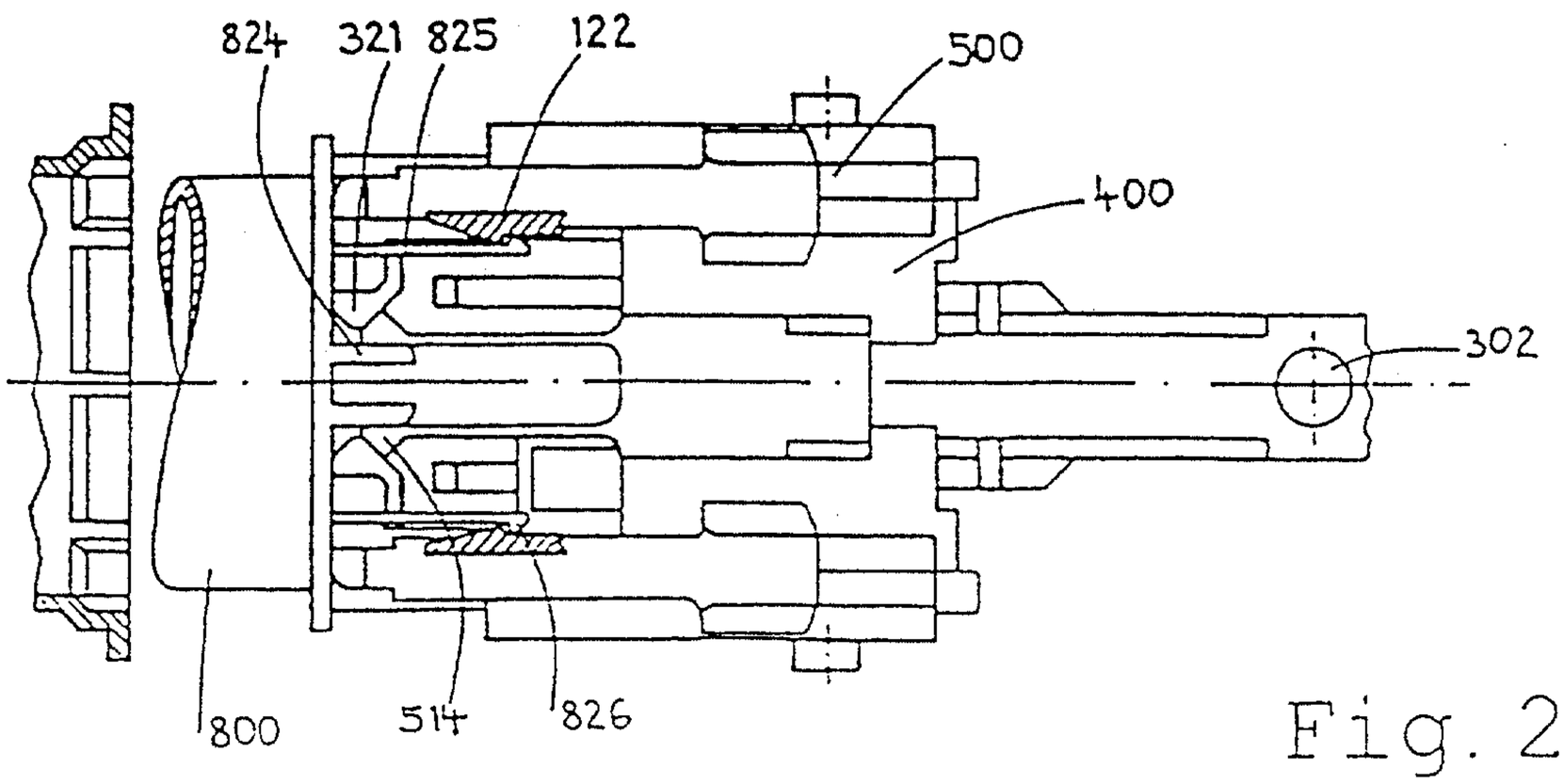


Fig. 20F



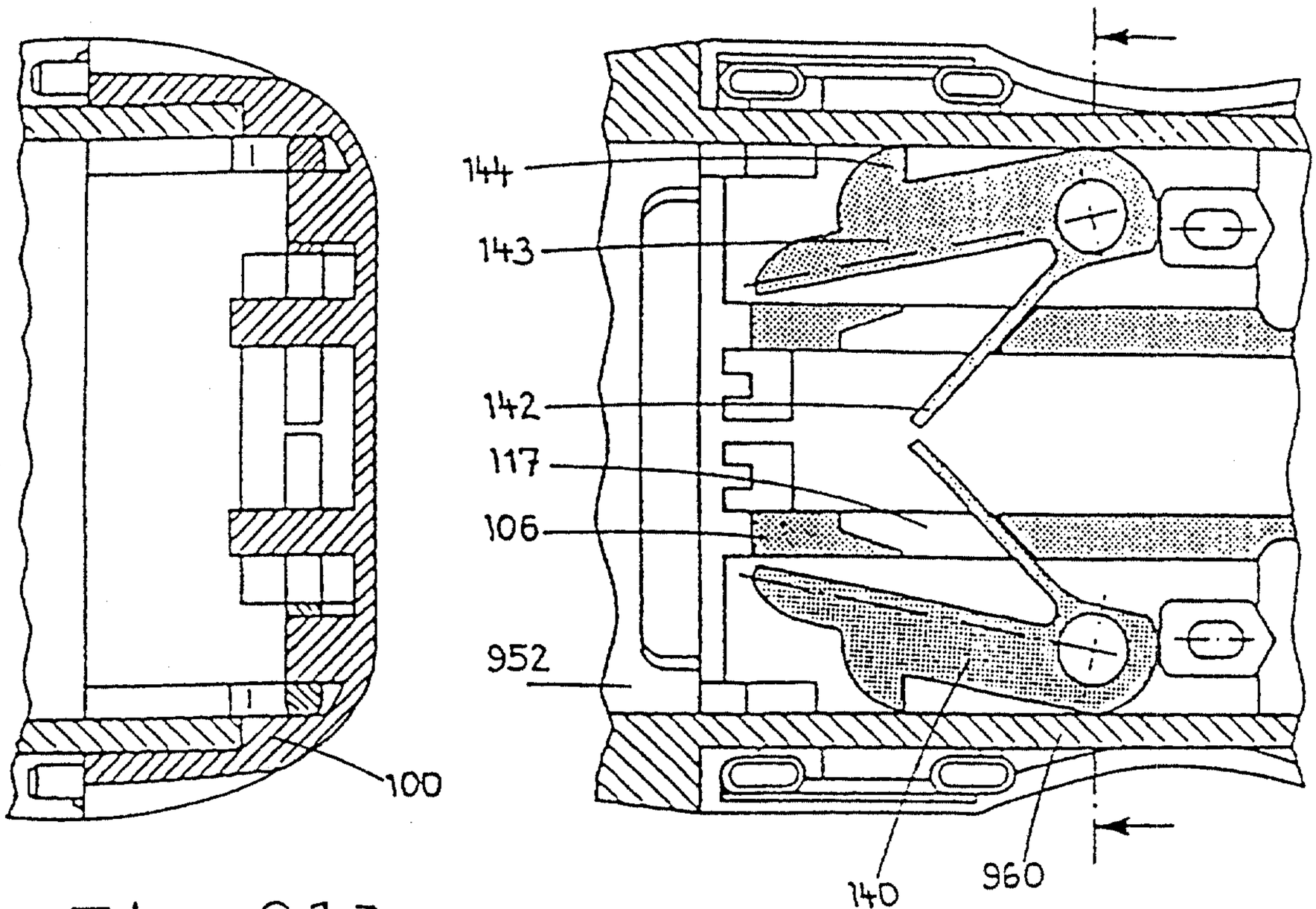


Fig. 21A

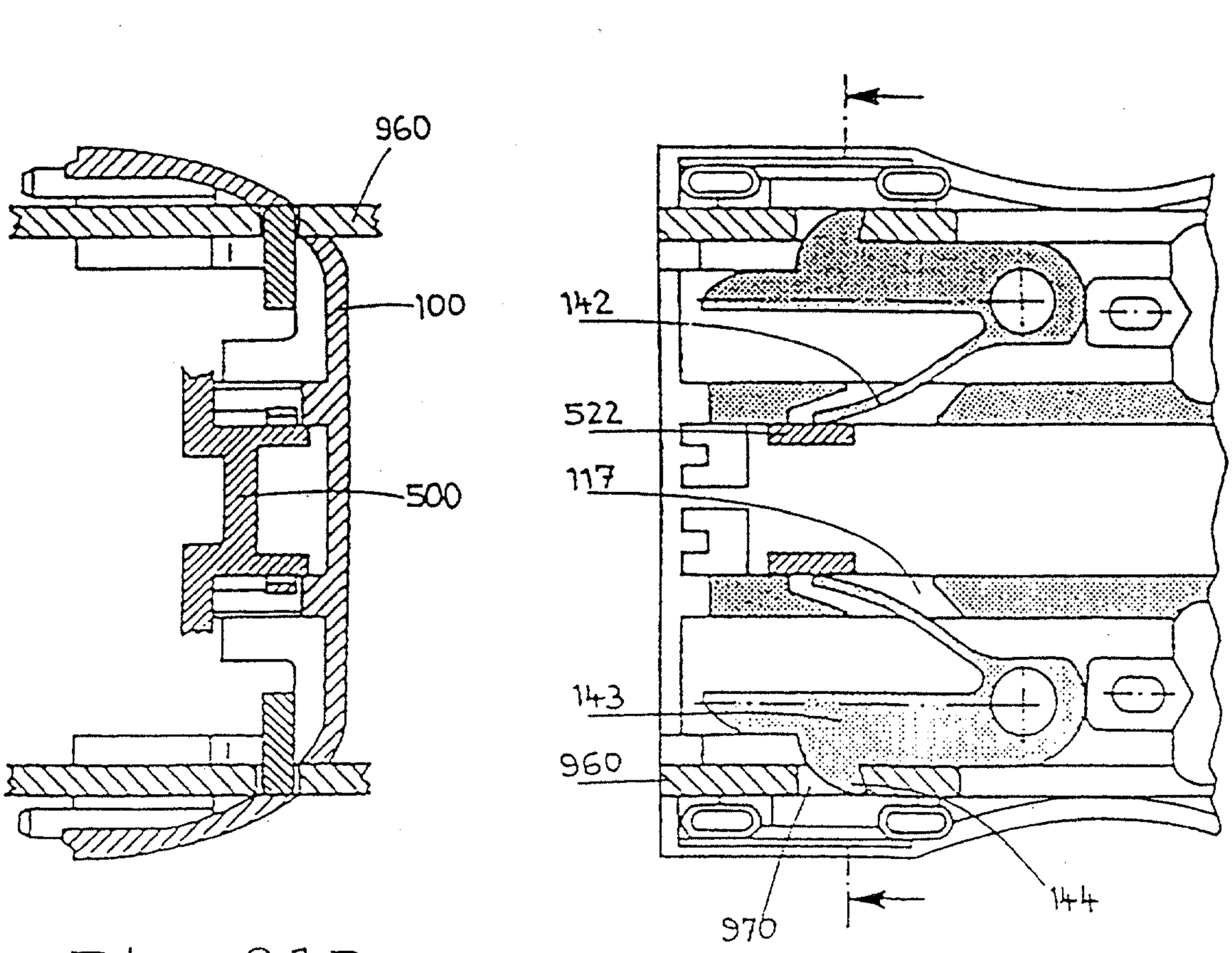


Fig. 21B

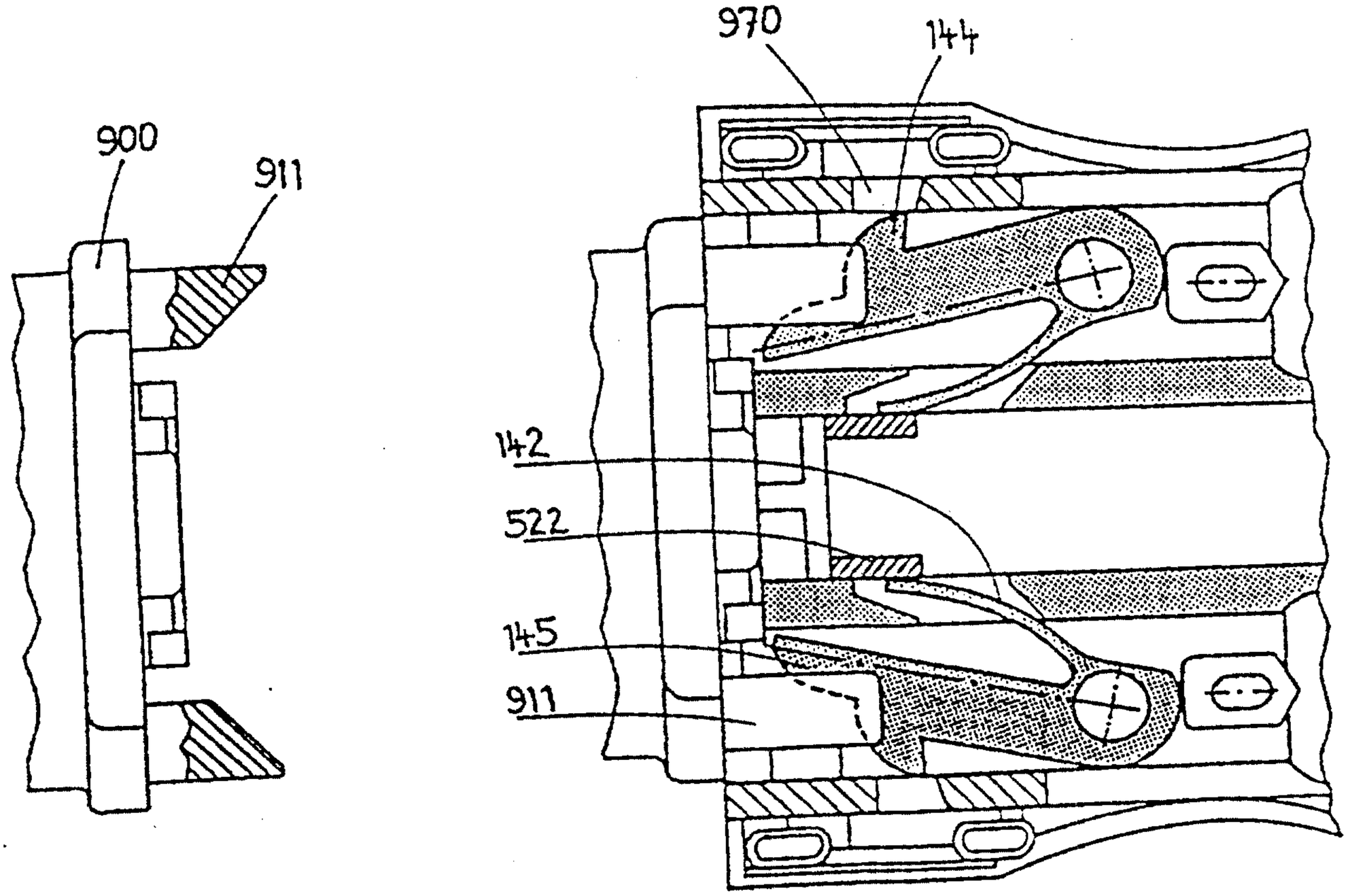
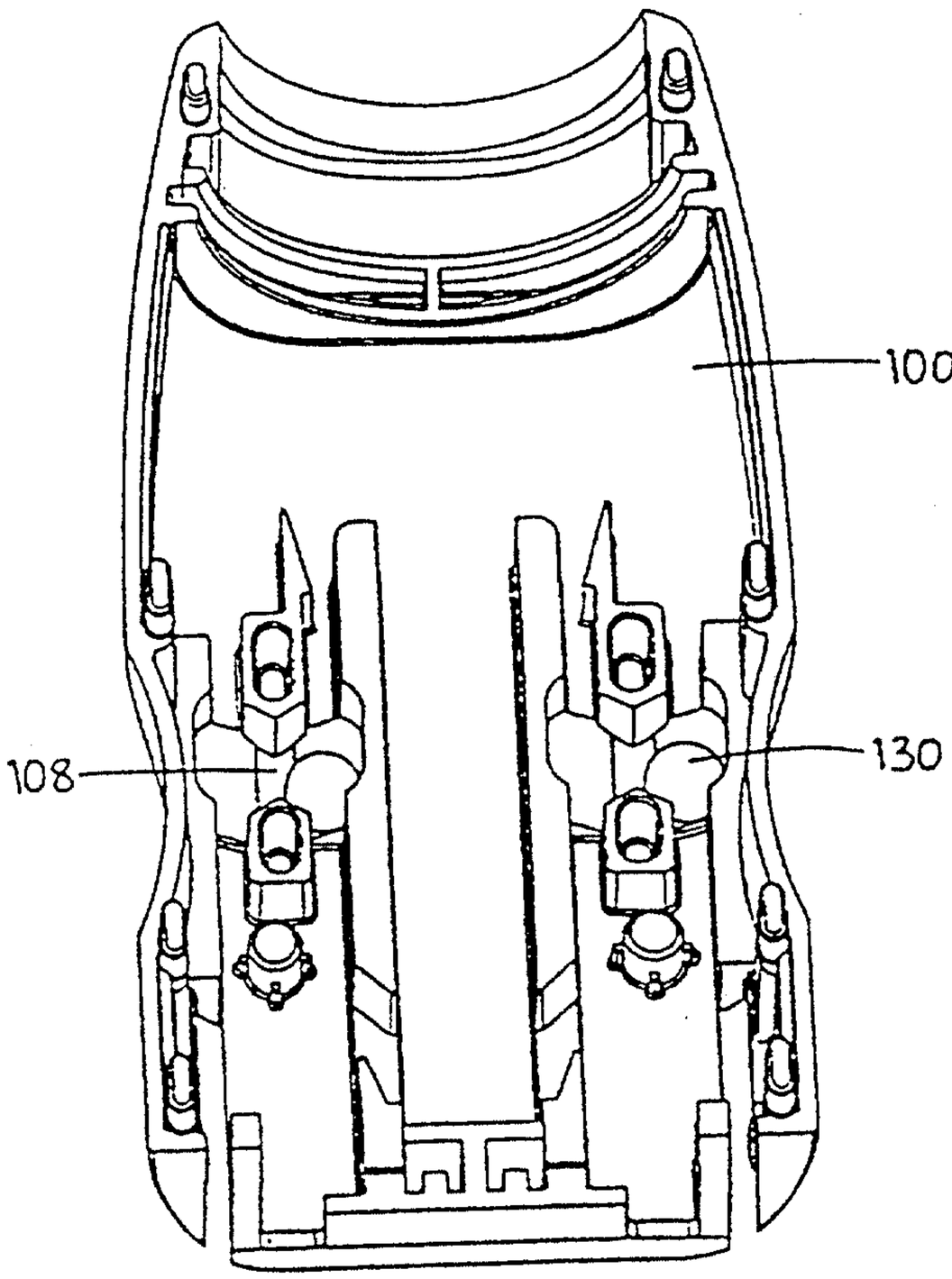


Fig. 21C

Fig. 22A



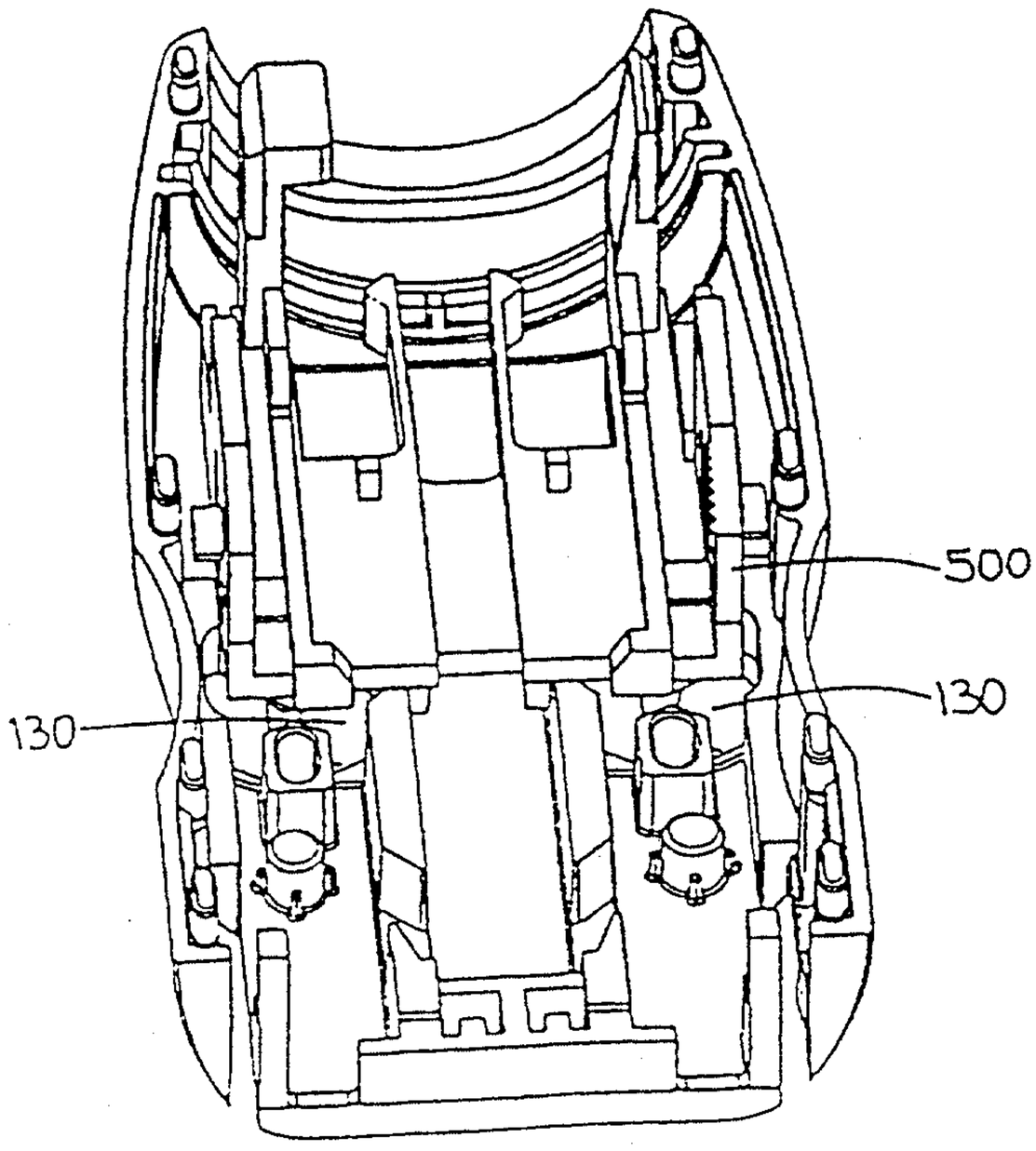
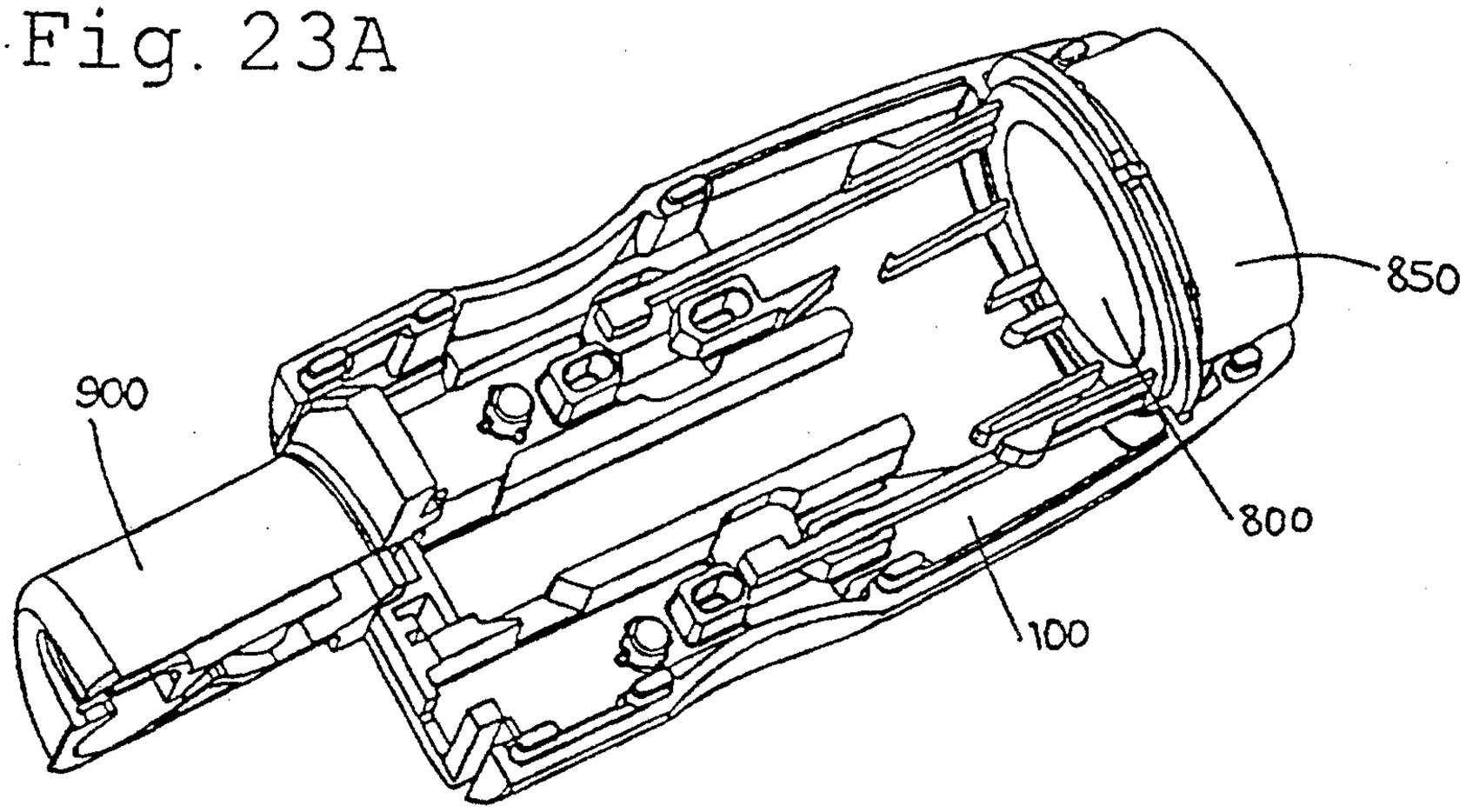


Fig. 22B

Fig. 23A



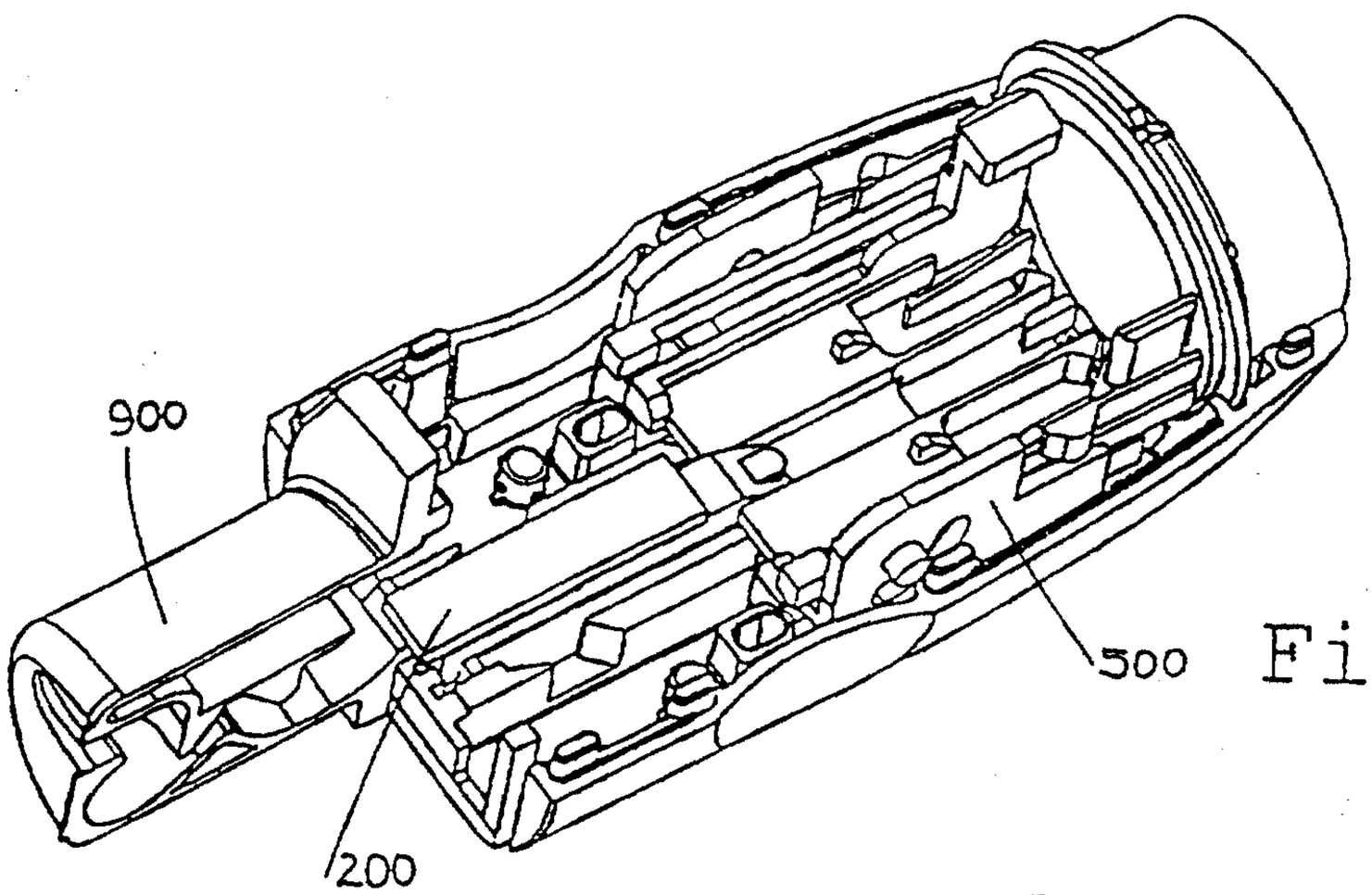


Fig. 23B

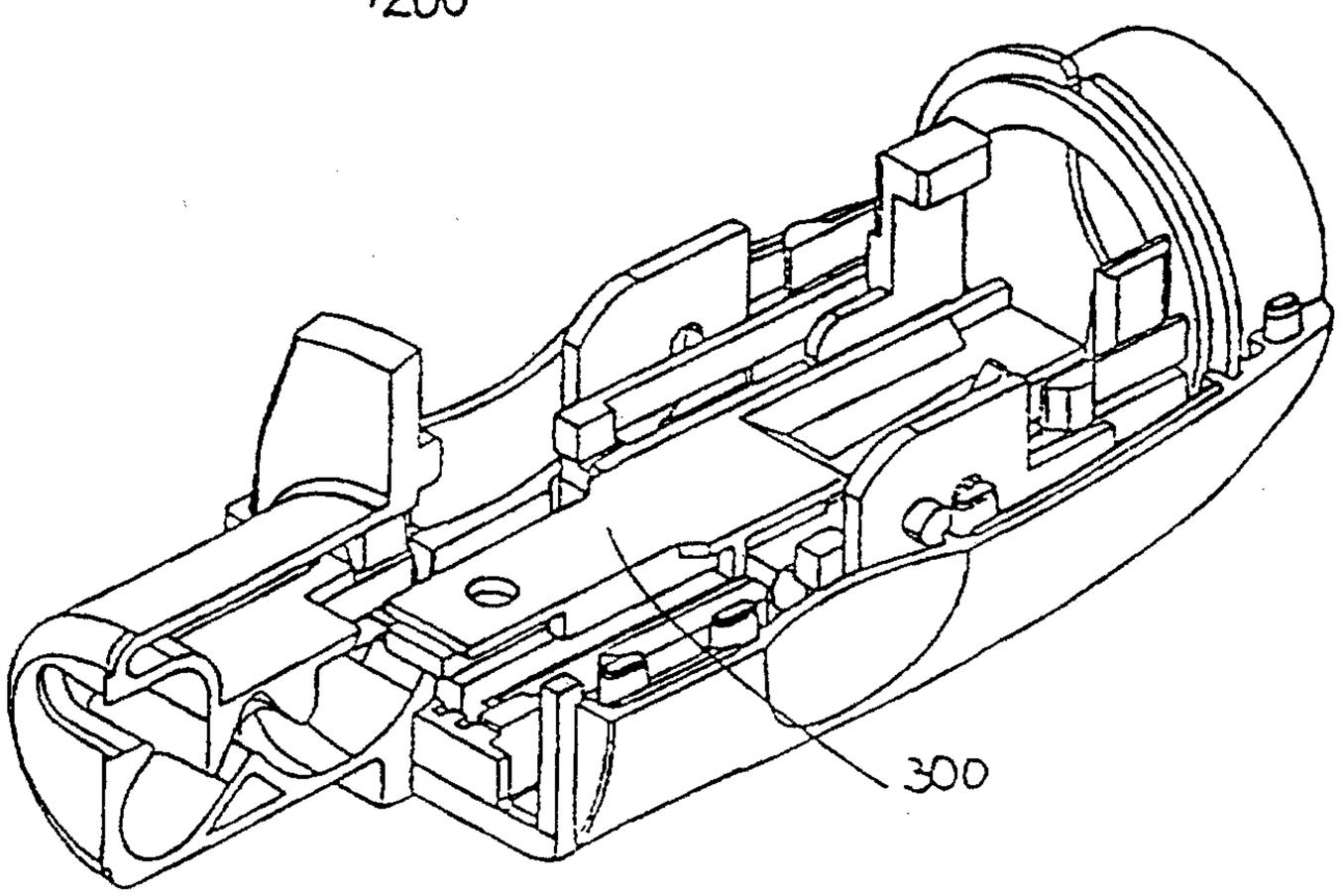


Fig. 23C

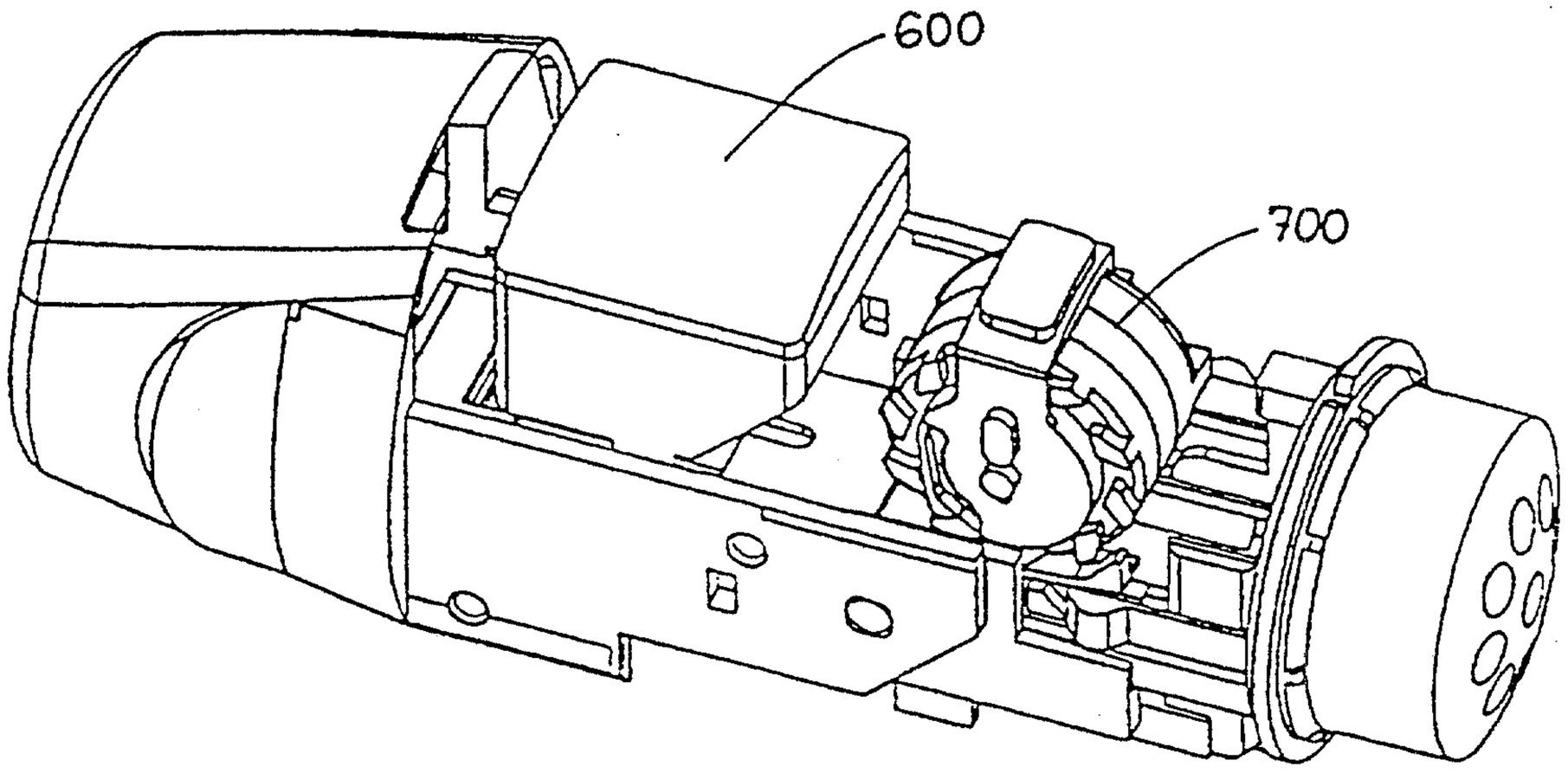


Fig. 23F

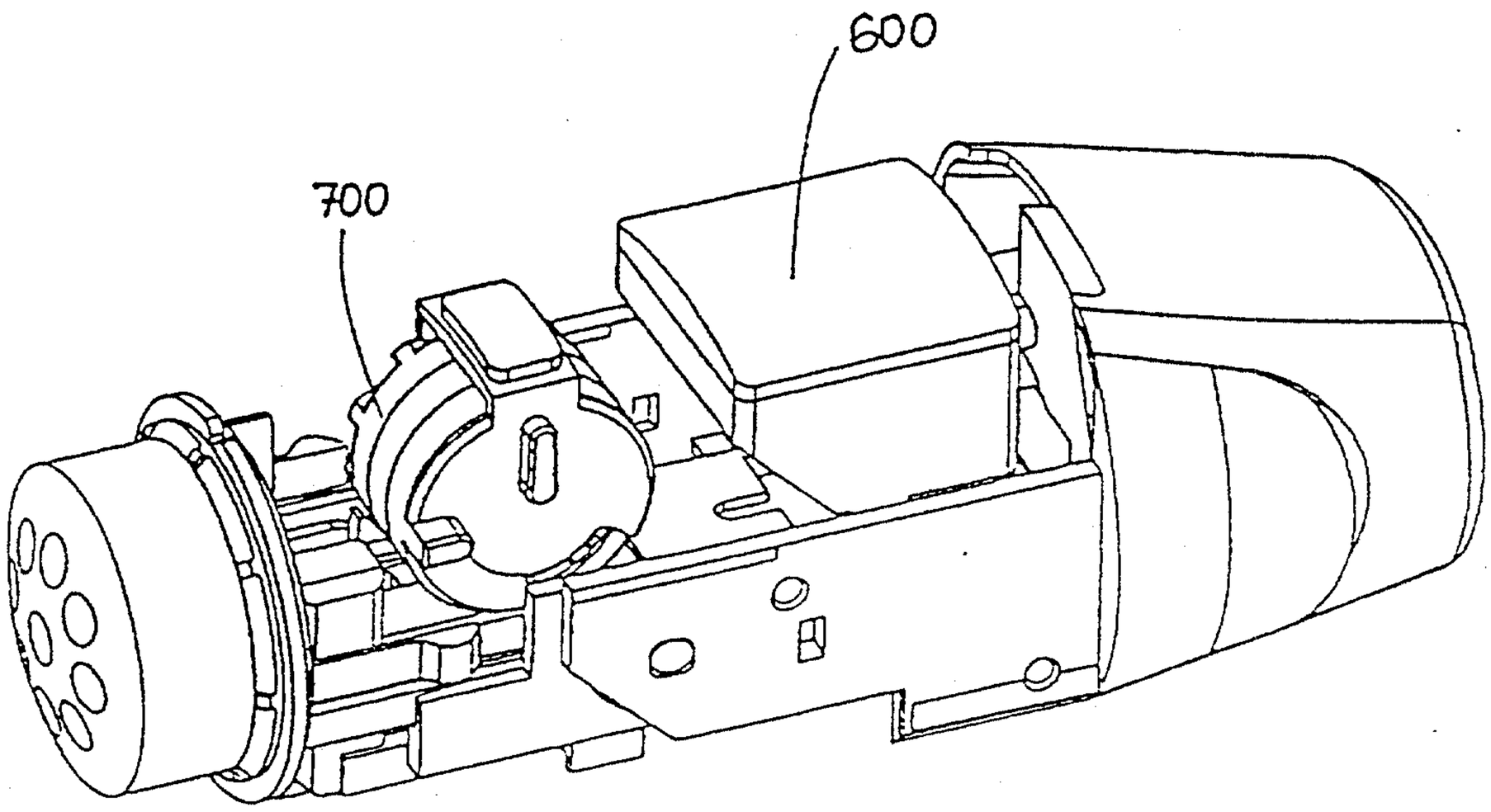
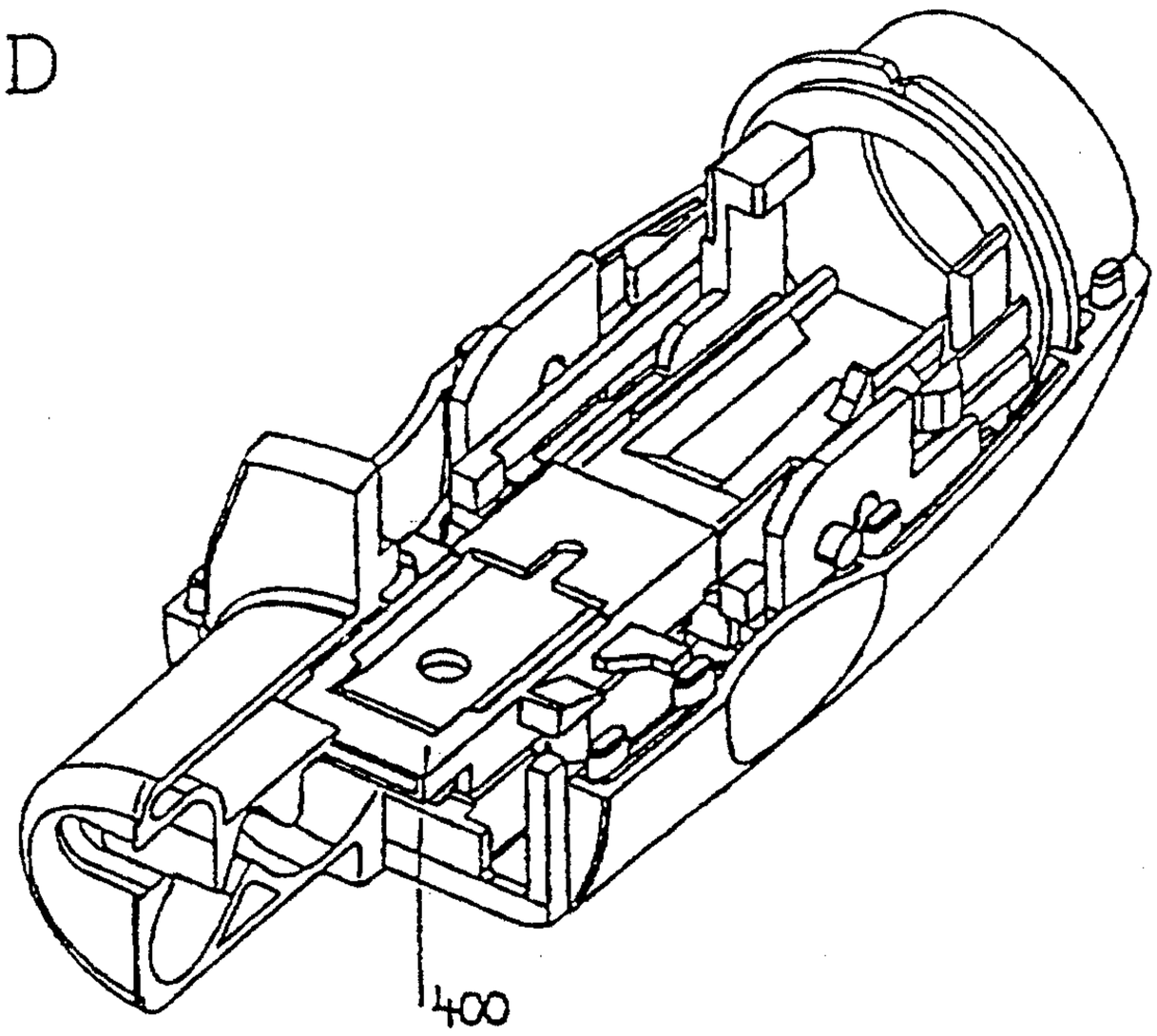


Fig. 23G

Fig. 23D



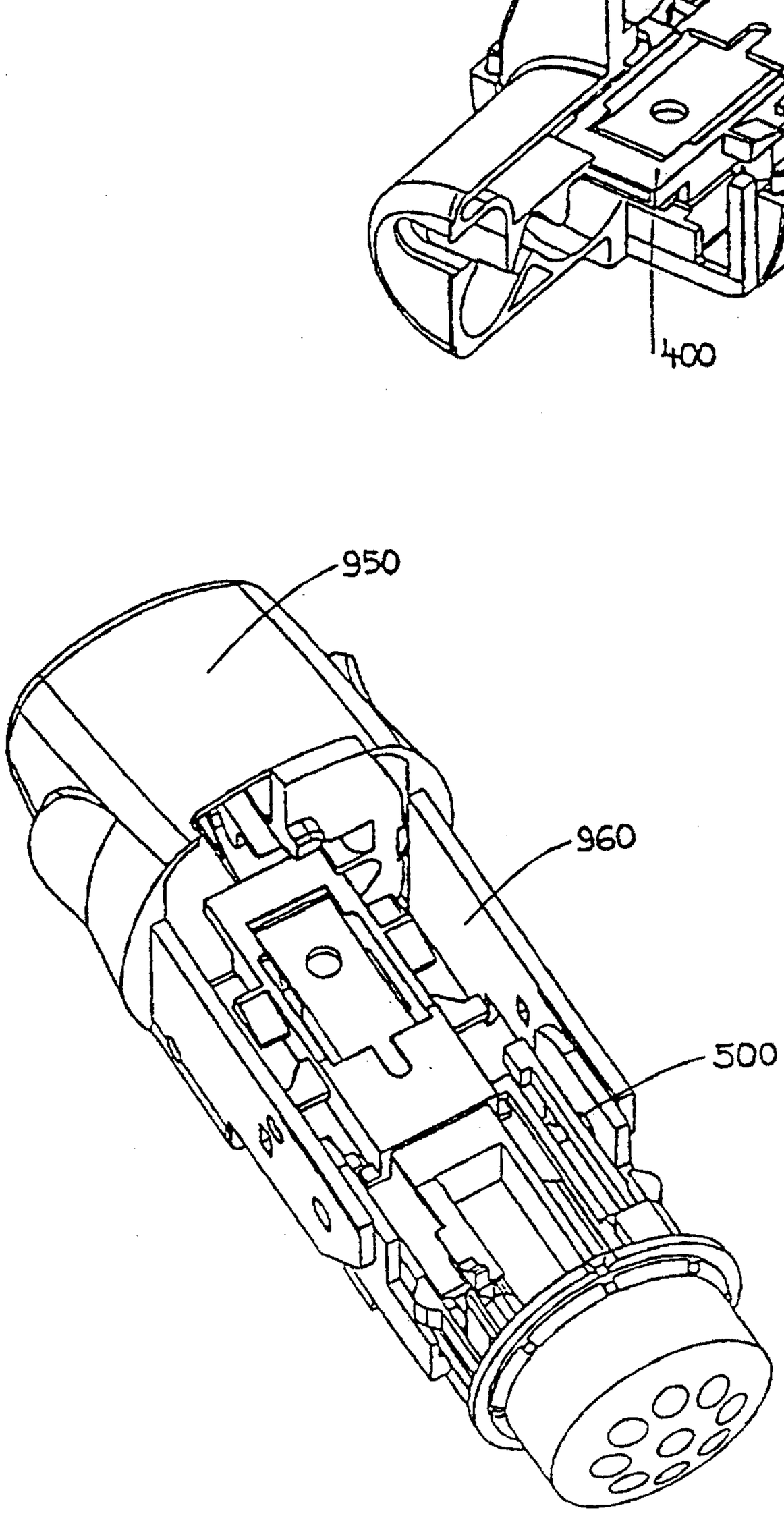
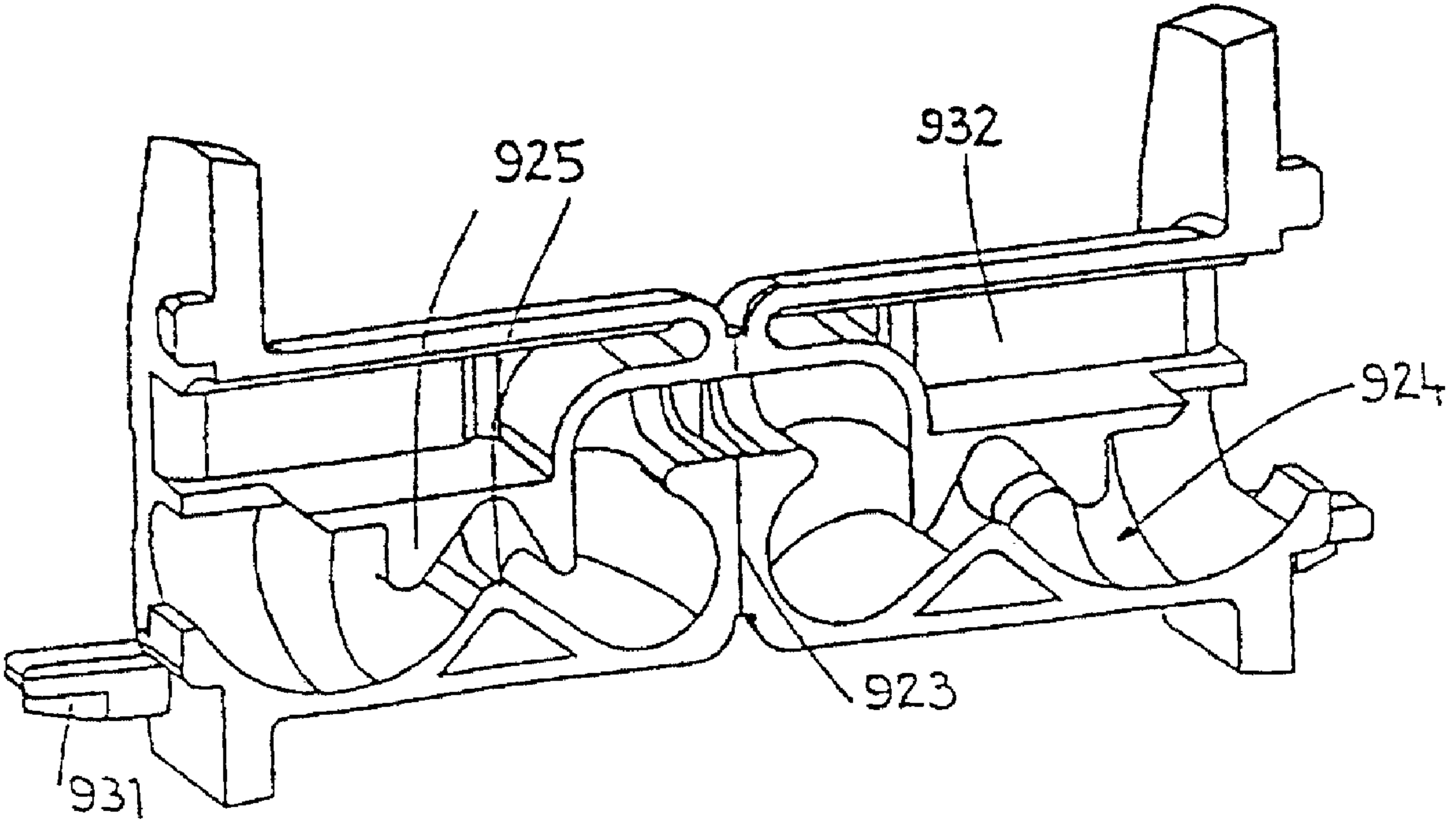


Fig. 23E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